Making stop smoking medications available and accessible: guidance and resources



NCSCT

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Authors: Hanifa Ditta and Louise Ross

Case studies from: Joanna Feeney, Juliana Goate and Georgina Crossman

Editor: Andy McEwen

Copy editor and proofing: Jane Stevens

Reviewers: Jo Locker (DHSC), Laura Mackenzie (DHSC), Sophia Papadakis (NCSCT), Joanna Feeney (Fresh+Balance), Juliana Goate (Smokefree Hampshire) and Georgina Crossman (Medway Council)

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1. Introduction

This briefing uses varenicline (both the generic versions and the proprietary Champix) as an **example of the processes needed to make stop smoking medications available to people who want so stop smoking**, including implementing a Patient Group Direction (PGD) locally. **The use of a PGD can reduce waiting times for getting medication, ease the burden on GP practices, and utilise community pharmacy services for effective health improvement.**

Smoking remains the leading cause of preventable illness, death and disability, and a leading driver of health inequalities in England.[1] Tackling tobacco dependency is one of the most effective ways of eliminating health inequalities.[2] **Local stop smoking services are extremely cost effective and play an important role, alongside other tobacco control policies, in driving down rates of smoking at national and local level.**[3]

First-choice stop smoking aids provide the greatest chance of success with quitting smoking (see Figure 1 on page 5) and are:

- combination NRT (use of an NRT patch plus a faster-acting NRT product)
- nicotine-containing vapes
- nicotine analogue medications (varenicline* and cytisinicline)

***Note: we refer to varenicline throughout to include both generic varenicline and Champix.**



NICE guidance NG209[4] includes varenicline as one of several medications that are recommended as 'first-line stop smoking aids'.

NICE National Institute for Health and Care Excellence

1.12.8

Advise people (as appropriate for their age) that the following options, when combined with behavioural support, are **more likely** to result in them successfully stopping smoking:

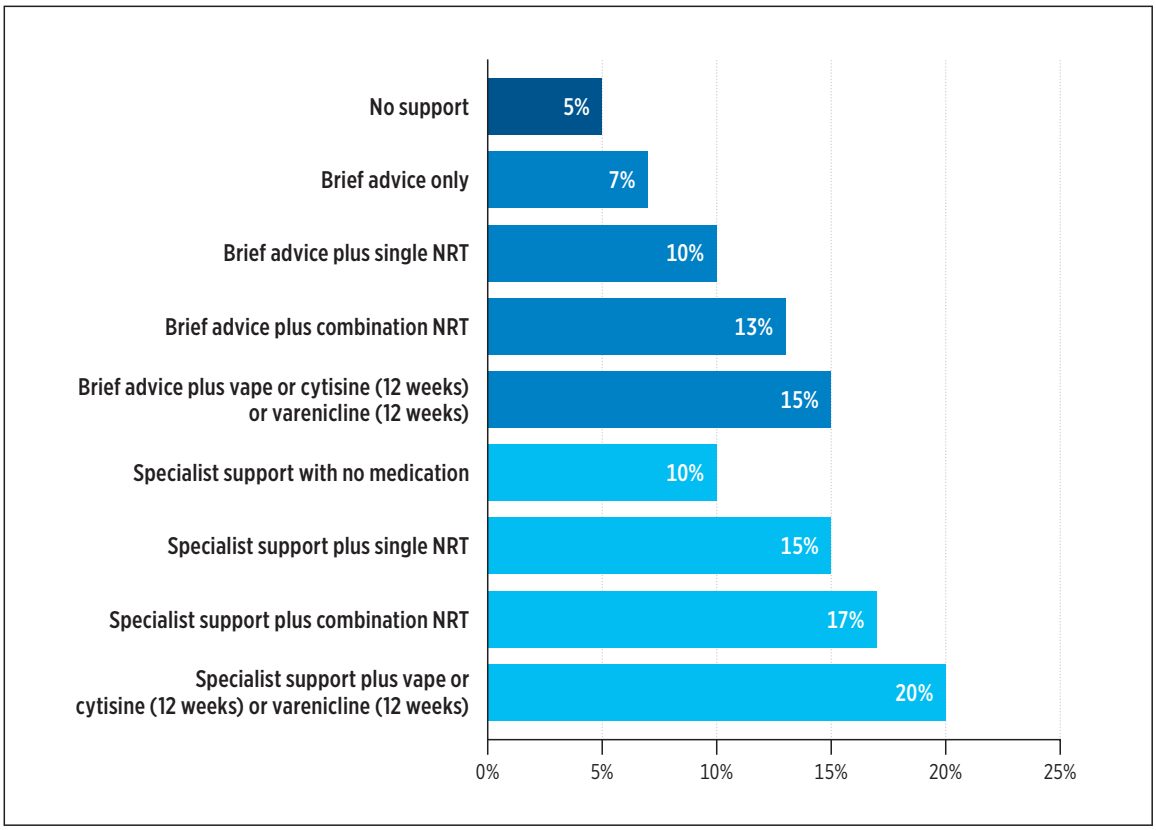
- cytisinicline [2025] *(Prescription only or PGD)*
- a combination of short-acting and long-acting NRT [2021] *(General Sales License or Over the Counter)*
- varenicline [2021] *(Prescription only or PGD)*
- nicotine-containing e-cigarettes [2021] *(Consumer product)*

1.12.9

Advise people (as appropriate for their age) that the options that are **less likely** to result in them successfully stopping smoking, when combined with behavioural support, are:

- bupropion *(Prescription only)*
- short-acting NRT used without long-acting NRT *(General Sales License or Over the Counter)*
- long-acting NRT used without short-acting NRT [2021] *(General Sales License or Over the Counter)*

Figure 1: Smoking abstinence rates for at least six months by treatment type[5]



Varenicline is a prescription-only medicine that first became available in the UK in 2006. It reduces nicotine withdrawal symptoms and urges to smoke and blocks some of the rewarding effects of smoking. **Varenicline is significantly more effective than single form NRT and bupropion, and slightly more effective than combination NRT.**[6]

There had been concerns in the past about the link between varenicline and neuropsychiatric and cardiac events. Large high-quality studies have provided evidence that there is no link between varenicline and suicidal ideation, adverse neuropsychological events or worsening of cardiac events.[7]

Varenicline is typically taken for 12 weeks. It can be extended by an additional 12 weeks (total 24 weeks) in abstinent individuals to prevent relapse.[8] It has been shown to be safe to extend treatment beyond 24 weeks to help maintain abstinence in clients who may benefit,[9] or as part of a Cut Down to Stop intervention.[10]

2. Principles of medication availability

Supporting access to all first-choice stop smoking aids via Local Stop Smoking Services (LSSS) for the full treatment course is best practice. This includes ensuring stop smoking aids are easy to access by removing barriers and being at low or no cost. The provision of free stop smoking aids has been shown to increase use of treatment, compliance and rates of stopping.[11] To ensure barriers to access and use of stop smoking aids are minimised, direct supply (having processes and protocols in place to provide stop smoking aids directly to clients at their appointments) is strongly recommended.

Quality issues resulted in the withdrawal of the branded version of varenicline (Champix) in 2021. Nitrosamine-compliant generic varenicline entered the market in the autumn of 2024[6] and nitrosamine-compliant Champix was reintroduced in the summer of 2025. **Ensuring access to varenicline will increase clients' chances of quitting successfully.** In local authorities, governance processes should be used to reinforce return on investment for treatment models/aids, that may on the face of it seem cost and resource intensive, but in the long run will pay dividends. At the minimum, local authorities should ensure that GPs are able and willing to prescribe varenicline at the request of LSSS, who will provide the necessary behavioral support. The national PGD for varenicline can also be adopted locally to improve access. **Use of the national varenicline PGD template for local supply will simplify access to the medication for clients who urgently need to stop smoking.** The PGD will enable clients to bypass a system that presents difficulties in getting an appointment with their GP.

PGDs allow specified healthcare professionals to supply and/or administer medications directly to a client with an identified clinical condition without the need for a prescription from a prescriber. A PGD can be used for varenicline. PGDs outline who is eligible to provide the medication, what criteria must be met, responsibilities of individuals covered under the PGD and necessary training and competency assessments. The individual healthcare professional authorised under the PGD is responsible for assessing that the client meets the criteria set out in the PGD. The supply and/or administration cannot be delegated.

3. Getting the medication onto the local formulary

There are no reasons why life-saving stop smoking medications should not be on the formulary. There is also no reason why, once on the formulary, these medications should have conditions attached to them which, in effect, prevent them being prescribed.

3.1 If there is more than one LSSS provider or commissioner in your locality, agree a lead organisation who will undertake this work with your Integrated Care Board (ICB) and create a *Memorandum of Understanding (MOU)* to formalise the collaborative approach.

3.2 You will need to contact your ICB Medicines Management Team to understand your local application and authorisation process.

3.3 The information needed for an application, in addition to that already stated on the PGD, includes product license status, supply route (who can prescribe and the pathway for prescribing), evidence base, and cost impact.

3.4 It will be important to establish whether the application needs to be completed and/or supported by a clinician.

3.5 You should also identify whether any local formulary decision making groups need to have input. Local groups may be in the form of a Trust Formulary Group, Drug and Therapeutic Committee or Area Prescribing Committee.

3.6 When you have prepared the application, submit it to the Medicines Management Team or other relevant local approvals panel for authorisation.

3.7 Communications to publicise the availability of the medication should be carefully planned.

3.8 A plan to support prescribers with training should be developed.

3.9 It should be noted that some clients may need to be referred to their GP for a prescription, if they are ineligible for the medication under a PGD. This will include individuals with more complex conditions, who should not be left without treatment. ICBs should ensure that GPs are willing and able to prescribe varenicline to clients who need to stop smoking and for whom this is the optimal choice of treatment.

4. Agreeing who will pay and how

4.1 The commissioner/provider should identify and agree an appropriate budget holder.

4.2 It will be helpful to create a cost-benefit analysis to support the proposal.

4.3 You should access the **British National Formulary (BNF)** to explore the availability and cost of the drug through different suppliers. The BNF will list all companies that have a license to market the product and will provide an indicative cost for different dosages and pack sizes. If the product is listed on the **NHS Drug Tariff**, this system can also be used as a guide for pharmacy supply reimbursement.

4.4 An important step will be to negotiate with the Local Pharmaceutical Committee for remuneration of pharmacy time. There is no national guidance on this, and it will be necessary to agree a mutually acceptable figure. If there are multiple Stop Smoking Service commissioners or providers within a locality, agree a lead organisation to undertake negotiations. A *Memorandum of Understanding (MOU)* can underpin this collaborative approach and will ensure consistency in payment agreements.
See Case Study 2 on pages 14 – 16.

4.5 You should review technology systems that support the payment process and ensure any invoicing mechanisms reflect the medication supply schedule. Services using **PharmOutcomes** will be able to use this platform to support data collection and invoicing.

5. Developing a localised Patient Group Direction (PGD) from a nationally produced PGD template

5.1 Refer to **NICE Guidance MPG2** for developing and authorising PGDs. This clarifies stakeholder participation, scopes of responsibility, oversight and governance.

5.2 **NHS England's PGD e-learning training** should be completed by those developing a PGD.

5.3 For nationally developed PGD templates, establish communication links with the relevant national body for guidance on any modifications needed at local level.

5.4 Set up a working group as set out in NICE Guidance MPG2 and create *Terms of Reference* for the group. If there are multiple stop smoking service providers or commissioners within a locality, it will be more efficient to have a collaborative approach to producing a unified PGD. This will also provide a consistent experience for service users accessing the medication.

5.5 Minutes of working group meetings must be submitted as part of the authorisation process.

5.6 Incorporate any local care and treatment pathways into the PGD, for example, the pathway(s) that need to be followed to ensure care planning is carried out for people on any of the medications listed in appendices B and C. This could be done by creating additional appendices to the main PGD document.

5.7 Check that pack sizes of medication support dosage regimens as set out in the PGD.

5.8 Submit the PGD, any supporting appendices, and minutes of working group meetings to relevant governance body for authorisation. **A local authority is legally able to authorise a PGD.**

5.9 Agree and set up a Service Level Agreement with each PGD supply organisation (if one is not already in place).

6. Implementing a PGD

6.1 Promote the PGD, for example with a launch event and communications plan.

6.2 Invite expressions of interest from healthcare professionals who are permitted to supply under the PGD. As of June 2024, pharmacy technicians can supply/administer medications under a PGD.[12]

6.3 All staff supplying and administering under the PGD must sign the relevant documentation.

6.4 Ensure all professionals involved in the PGD supply process complete the training listed in the PGD document. This should include any local training such as safeguarding and other refresher training.

6.5 Any other staff groups impacted by the PGD should have their training needs met.

6.6 Review any existing protocols that are impacted by the PGD and ensure they are updated where necessary.

6.7 Have a plan in place to implement a system for monitoring, auditing and reviewing the PGD.

6.8 Update or activate technology platforms that support the invoicing process for PGD supply organisations.

7. Resources

Varenicline: medicinal forms
Information on varenicline formulations, pack sizes, distributors and costs
bnf.nice.org.uk/drugs/varenicline/medicinal-forms

Varenicline: summary of product characteristics
Up to date and approved information for licensed medicines.
Simply search for 'varenicline' here: www.medicines.org.uk/emc

Varenicline: considerations for stop smoking service providers
This resource includes a checklist of actions to support stop smoking service providers when introducing varenicline into their treatment model. The publication addresses some of the key questions on the use of varenicline in people with mental health conditions and cardiovascular disease, and signposts to additional sources of information. www.ncsct.co.uk/publications/category/varenicline

NHS Specialist Pharmacy Service
A point of reference for pharmacists and clinicians for advice on medicines. A copy of the nationally produced varenicline PGD template is available on this website.
www.sps.nhs.uk/articles/varenicline-for-smoking-cessation

NICE Guidance for Patient Group Directions
Guidelines for good practice in developing, authorising, using and updating Patient Group Directions. It provides clarity on setting up working groups, who needs to be involved, and which organisations can authorise PGDs. It also sets out scopes of responsibility for the professionals involved. www.nice.org.uk/guidance/mpg2

Drug Tariffs for generic drugs supplied through pharmacies in England and Wales
Annually published resource setting out the amount pharmacies receive from the NHS for generic prescription medicines. www.drugtariff.nhsbsa.nhs.uk

PharmOutcomes
A web-based system for pharmacies to record and report on healthcare interventions delivered. It can also be used to manage pharmacy remuneration and reimbursement for contracted services. https://pharmoutcomes.org

E-learning for Patient Group Directions
Online training course for healthcare professionals involved in the development, authorisation and implementation of PGDs. The course outlines legislative requirements and signposts users to other learning resources.
www.e-lfh.org.uk/programmes/patient-group-directions

Stop smoking practitioner training
A range of training modules, including behavioural support to accompany the use of stop smoking aids. A specialist module is available for those supporting clients with mental health diagnoses. https://elearning.ncsct.co.uk/england

Pharmacy specific training
The Centre for Pharmacy Postgraduate Education provides an online resource for pharmacists and pharmacy technicians. It includes training modules relevant to PGD supply processes and includes links to additional training sources through organisations such as the NCSCT and NHS E-learning for healthcare.
www.cppe.ac.uk/gateway/smoking

CASE STUDY

Case Study 1:

Medway Council

Medway Council provides an in-house stop smoking service and we have, in the past, had Champix available through a PGD.

Historically, we have worked with the CCG (now ICB) Medicines Management team to develop the PGD which would then be authorised through the CCG/ICB's governance process.

GPs in Medway are unable to prescribe varenicline so getting the medication available via a PGD is particularly important for us. In starting our work on the PGD, we liaised with our colleagues in the ICB to understand what role, if any, they needed to have in the process.

We were pleased to discover that local authorities are classified as an 'authorising body' and are legally able to authorise a PGD. This streamlined our work as we no longer needed to include ICB colleagues in the working group or take the PGD through their authorisation process.

Our working group core membership was small and comprised a project manager, clinician, pharmacist, Local Pharmaceutical Committee (LPC) lead, the stop smoking service's pharmacy relationship officer and stop smoking service lead. Guest members were brought in when we needed specialist input, for example where mental health medication pathways were discussed.

There were some modifications made to the nationally produced PGD template, and these changes reflected local pathways and services. We remained in regular email contact (**asksps.nhs@sps.direct**) with a team member at the Specialist Pharmacy Service to discuss any modifications. The service was incredibly supportive and responded quickly to our questions.

We started the scoping element of the PGD development work in early November. Our working group met five times from mid-November through to end of January and the PGD was signed off in February. We negotiated pharmacy reimbursement costs via the LPC and communicated the PGD formally to pharmacies and GPs at the end of February.

Georgina Crossman
Senior Public Health Manager
Medway Council

CASE STUDY

Case Study 2:

North East Regional PGD Supply Service

Overview

A regional initiative across 11 of 12 Local Authority (LA) areas in North East England establishing a **Pharmacy PGD Supply Service** to integrate varenicline and cytisinicline into Stop Smoking Services (SSS). A collaborative effort involving **Fresh, Public Health Pharmacists, LA Tobacco Commissioners, North East and North Cumbria (NENC) ICB Clinical Lead** and **Pharmacy Services North East (PSNE)** addressed prescription barriers, formulary inconsistencies and healthcare provider capacity constraints. The new Pharmacy PGD Supply service aims to ensure all Stop Smoking Services across the region can independently provide the most effective stop smoking aids, delivering greater efficiencies, cost savings, improved quit success rates and a more streamlined, region-wide approach to service delivery.

Objectives

- Enable **all 11 LA Stop Smoking Services** to independently provide **varenicline and cytisine**
- Implement a **regional Pharmacy PGD supply service**
- Improve efficiency and reduce costs through standardisation

Approach

- Mapped local SSS medication provision processes
- Gathered feedback from key stakeholders
- Reviewed previous varenicline PGDs and other pharmacy dispensing tariffs
- Developed a cost-impact model to assess benefits of utilising PGD
- Scoping paper to ADPHNE Tobacco Commissioners network

Stakeholders

- Fresh
- LA Tobacco Commissioners
- Public Health Pharmacists
- PSNE
- Stop Smoking Service Providers
- Primary Care
- Local Pharmaceutical Committee (LPC)
- ICB Formulary Advisory Group

Development and implementation

A Task & Finish group of key stakeholders led the development of a regional Pharmacy PGD supply service by:

- Considered feedback from Primary Care and ICB Formulary Advisory Group in relation to prescribing capacity restraints
- Reviewing past PGD models and NRT voucher schemes
- Developing a cost-impact model projecting a **8% cost reduction** and **4% increase in quit rates** (~653 additional quitters in the year 2025/26)
- Agreeing standardised pricing with LAs and LPCs: management fee of **£50 per pharmacy, £12.50 per clinical assessment** and **£2.50 per supply fee**
- Identifying a lead LA to contract PSNE on behalf of all 11 LAs through a Memorandum of Understanding (MoU)
- Developing a regional PGD from the national template, authorised by the lead LA and adopted across all LAs
- Development of PharmOutcomes module, including an **e-recommendation form** for Stop Smoking Advisors
- PSNE invited 555 eligible pharmacies to deliver the service via a **Service Level Agreement (SLA)**, prioritising the 420 already delivering NRT voucher schemes
- Developed a standardised training program, including live session, training videos and online learning module
- PSNE manages pharmacy supply and invoicing, reducing administrative burdens by consolidating invoices from multiple pharmacies for each LA into a single monthly invoice
- Ongoing review monitored with PSNE and via the North East Tobacco Commissioners Network

Benefits

- **Local Authorities:** Reduced administration, cost efficiencies, standardised training
- **Pharmacies:** Consistent processes and payment structure, increased engagement
- **Service Users:** Easier access to effective medication, removal of geographical boundaries resulting in increased flexibility and choice

Challenges and solutions

1. **Concerns about primary care engagement and capacity:**
   Addressed by shifting responsibility to pharmacy services
2. **Lack of regional consistency:** Introduced a unified PGD model
3. **Training and operational complexities:**
   Standardised training and processes across the region
4. **Regional Procurement:**
   Collaborative working and involvement of local procurement/legal teams
5. **Timelines:** Flexibility and frequent communication/updates to all stakeholders

System wide working

A parallel workstream is underway within NHS with Trusts adapting a template Standard Operating Procedures to implement, to enable the provision of varenicline in Inpatient Tobacco Dependency Treatment Services.

Conclusion

The North East Regional PGD Supply Service enhances accessibility, reduces GP dependency and increases quit success rates. Its collaborative structure ensures long-term sustainability and serves as a model for other regions.

Joanna Feeney
Stop Smoking System Strategic Manager
Fresh+Balance

CASE STUDY

Case Study 3:
Smokefree Hampshire

A few years ago, I used PharmOutcomes to refer clients for Champix under a PGD, and more recently, I've used it for pharmacy referrals for varenicline.

In my local SSS, stop-smoking advisors are now using PharmOutcomes to refer clients to pharmacists. Once a client is referred to a selected pharmacy, the provider receives a notification email with the referral. This ensures that no referrals are lost or delayed. Pharmacists can then record their client assessments and document the supply of varenicline directly on the system.

Pharmacies can invoice through PharmOutcomes, benefiting from accurate, time-saving and automated invoicing.

Every pharmacy I've worked with has embraced PharmOutcomes, and implementing the PGD service for varenicline through the platform has proven to be much more efficient compared to paper referrals and invoicing.

To implement a PGD service for varenicline, the first step is ensuring a valid PGD is in place. Then, it's important to identify pharmacies willing to collaborate and supply varenicline under the PGD. Once that's set, training is provided to the advisor team on the PGD process – this can vary across stop smoking services, but generally includes a client health check, a suitability assessment for varenicline and client registration on PharmOutcomes.

Once the advisor team is trained, the pharmacy provider list should be shared with the team and added to PharmOutcomes. Referrals can then be made, and pharmacists conduct assessments, log consultations and add the medication to the client's record on PharmOutcomes. This structured process saves time, ensures accurate documentation and enhances client care.

It is worth noting though that if a tender process is underway, with the possibility of a change of provider, it may be worth delaying implementation so that any procedural or legal matters can be confirmed with the new provider.

Juliana Goate
GP and Pharmacy Stop Smoking Manager
Smokefree Hampshire

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