



PSNE Ltd

NENC stop smoking PGD service

Valid from 1st August 2025

Service background

This service is commissioned by PSNE on behalf of participating local authorities in the North-East region (with Middlesbrough Council acting as the lead local authority commissioner of PSNE).

This service covers the recommendation to supply POM stop smoking medication from participating stop smoking services to commissioned pharmacies under patient group direction (PGD) and via an e-recommendation on PharmOutcomes in the participating local authority areas listed on the pharmacy PharmOutcomes template.

See Appendix 1 which describes how this service fits in with other commissioned pharmacy stop smoking services.

Aims and intended outcomes

Aims

- To supply POM stop smoking medication to clients who are engaged with a participating local authority stop smoking service in the North-East region via an e-recommendation from a stop smoking service adviser to a commissioned community pharmacy on PharmOutcomes.
- A PGD supply service for POM stop smoking medication across participating localities in the North-East region will allow stop smoking services to make recommendations via PharmOutcomes to commissioned pharmacies to supply this medicine to clients and will allow clients to choose which pharmacy they wish to access the supply from regardless of whether a pharmacy is in the same local authority as the stop smoking service.

Objectives

- Commissioned community pharmacies utilise PharmOutcomes to receive an e-recommendation to supply POM stop smoking medication from participating North-East local authority stop smoking advisers for clients receiving behavioural support as part of a structured quit attempt.
- Community pharmacists consider the suitability of the e-recommendation to supply against the criteria in the service PGD.
- Community pharmacy supplies POM stop smoking medication to clients receiving behavioural support from participating North-East local authority stop smoking service advisers and provides additional advice on how best to use the medication.
- Community pharmacy provides general encouragement to clients to help them maintain their quit attempt but are not required to provide behavioural support.

Service description

The receiving pharmacy will:

- Receive the e-recommendation (Appendix 2) to supply POM stop smoking medication, via PharmOutcomes. This referral will be titled Varenicline or Cytisine PGD e-recommendation to pharmacy. The e-recommendation for POM stop smoking medication will be for a 2-weekly supply.
- Complete each e-recommendation within 1 week of receipt. The registered pharmacy healthcare professional will complete the clinical check as to the suitability of supply in line with the requirements in the accompanying PGD. **The registered pharmacy healthcare**

professional will make the final decision and takes responsibility as to whether the medication is supplied or not (Appendix 3 for a summary of key requirements in the accompanying PGD and a copy of the PharmOutcomes GP practice email following each supply of POM stop smoking medication).

- Undertake consultations/clinical checks with the client by phone or video call if the client is unable to collect in person, particularly for a first supply to the client.
- Check that the client or their representative is collecting the medication within 1 week of the e-recommendation being issued and if the client normally pays for NHS prescriptions.
- If supplying:
 1. Label the medication in the normal dispensing manner within the patient medication record.
 2. Advise the client about the medication e.g. how to take it, side effects, etc. The pharmacy is asked to provide general encouragement with a client quit and answer any queries they have.
 3. Document on PharmOutcomes within 1 day of supply so that the stop smoking adviser is aware and the client's GP practice receives an email notification of supply via PharmOutcomes.
- The pharmacy has the option of rejecting an e-recommendation on PharmOutcomes and describing the reason why, for example:
 1. The client has not attended the pharmacy to collect their medication within 1 week of the e-recommendation being generated and therefore being received by the pharmacy.
 2. The registered pharmacy healthcare professional has assessed the client to be unsuitable for the requested medication. The pharmacy should inform the client that the stop smoking adviser will be back in touch to review their treatment plan.

Notes:

- Each e-recommendation only requests one issue of medication and cannot be used for multiple supplies of POM stop smoking medication.
- The client's ongoing behavioural support and pharmacotherapy review will be provided by the stop smoking service adviser, however for ongoing supplies of POM stop smoking medication, pharmacies should continue to check if the client has had any side effects and that ongoing supplies are still suitable in line with the requirements in the PGD.
- All assessments and supplies must be documented on PharmOutcomes. Records should be kept for a minimum period in line with standard clinical governance requirements.
- Following a POM stop smoking medication supply, it is the pharmacies responsibility to directly contact the stop smoking service adviser if the client's GP practice subsequently raises concerns about the supply (Note: The accompanying PGD states that GP practices should be informed in advance of a quit attempt. This is achieved by the automatic PharmOutcomes email sent to the client's GP practice for each POM stop smoking medication supply which, in the case of the starter pack, is 1 week before the client will begin their quit attempt on day 8-14 of the starter pack).

Service standards

Applicable service standards

The pharmacy contractor will ensure that the:

- Service is delivered in line with the NHS (Pharmaceutical Services) Regulations 2013 and the NHS Community Pharmacy Contractual Framework.
- Most recent guidance on medicines from the Medicines and Healthcare products Regulatory Agency (MHRA) is adhered to.
- General Pharmaceutical Council's Standards for Pharmacy Professionals and Pharmacy Premises is adhered to.

Training and competency requirements for pharmacy staff

It is the duty of the pharmacy contractor to ensure that the service is delivered by staff who have the necessary training and competence in this intervention and that all pharmacists and registered pharmacy technicians have signed the PGD authorisation form (there is no requirement to send copies of the authorised PGD back to PSNE).

Pharmacy lead:

- The pharmacy will have a named pharmacist or registered pharmacy technician who is the lead for providing this service (if this individual leaves an alternative must be nominated within 2 weeks).
- The pharmacy lead will ensure that all relevant staff members are aware of this service, that e-recommendations will be received via PharmOutcomes and the actions that need to be taken.

All pharmacists and registered pharmacy technicians working under the PGD will:

- Consider the operational requirements in this service specification and any subsequent updates – the latest version will be included in the PharmOutcomes template.
- Consider the clinical requirements in the accompanying PGD and ensure they are competent¹ and authorised to work under the PGD (and any subsequent updates – the latest version will be included in the PharmOutcomes template).
- Consider Appendix 3 in this service specification which summarises the key requirements in the accompanying PGD and shows a copy of the PharmOutcomes GP practice email following each supply of POM stop smoking medication.

A PharmOutcomes Declaration needs to be completed for each staff member accessing the claims template (Appendix 4 for the template PharmOutcomes Declaration).

Facilities, stock, delivery and operating procedures

- Accredited pharmacies will have a suitable private consultation room which is available for client consultations.
- Pharmacies will keep POM stop smoking medication in stock.
- Standard operating procedures and clinical governance processes for this service should be set up and adhered to at all times to assure patient safety.

Incident reporting

- A summary of incidents or complaints should be reported to the service commissioner PSNE upon request. The contractor will inform the commissioner with a summary of the incident/complaint(s) and an action plan for ensuring any such incidents/complaints can be avoided in the future and how lessons have been learnt.

Population covered

- Any client aged 18 years or over who is registered with a North-East general practitioner or resident or working within the North-East and who has had an e-recommendation to supply issued by a participating North-East stop smoking service.
- As this service covers the North-East region, clients resident in one local authority may access the service in pharmacies in a different participating local authority to the one they live in.

Exclusions

- Clients under the age of 18 years.

¹ See NICE competency framework for health professionals using PGDs at www.nice.org.uk/guidance/mpg2/resources.
Recommended training at <https://www.e-lfh.org.uk/programmes/patient-group-directions/>.

- Clients not registered with a North-East GP practice or residing or working in the North-East region.
- Clients who do not consent to share information about their medication supply with their GP and anonymised information with PSNE.
- Where there are contra-indications to treatment following the clinical assessment as described in the accompanying PGD (see also summary in Appendix 3).

Accessibility

- The service will be available throughout the pharmacy's opening hours (both core and supplementary).
- The pharmacy contractor will maintain an acceptable level of staffing at all times and will provide suitably accredited, skilled, trained and experienced staff to provide the service.

Data collection

e-recommendations are processed via PharmOutcomes. All fields must be complete and accurate. For pharmacies

- Complete the e-recommendation on PharmOutcomes within 1 day of supply so that the stop smoking adviser is aware and the client's GP practice receives an email notification of supply via PharmOutcomes (Note: This is particularly important for the supply of the starter pack in order to inform the GP practice 1 week before a client quit attempt).

PharmOutcomes generates an invoice to PSNE on a monthly basis. PSNE then generates monthly invoices to local authorities based on where the stop smoking service is based. This selection is made by the pharmacy selecting from the local authority listing on PharmOutcomes.

Payment

The pharmacy contractor will be paid at the following rates:

Duty	Fee
1. Clinical assessment fee for a week 1-2 supply e-recommendation for POM stop smoking medication	£12.50 ex VAT
2. Dispensing fee for each supply	£2.50 ex VAT
3. Medication cost	Drug tariff product cost ²

In the event of over claims being made, PSNE has the right to reclaim all monies.

Notice period

A minimum of 1 month notice is to be provided by either the contractor or PSNE in the event of any decision to withdraw from this service before the stated expiry date.

² VAT-free when supplied under a community pharmacy PGD.

Appendix 1: How this service fits in with NRT provision from community pharmacy

Pharmacies can provide NRT as part of three separate commissioned services:

1. From the national community pharmacy Smoking Cessation Service: The pharmacy directly supplies NRT free of charge following a secondary care referral and discharge from hospital (<https://cpe.org.uk/national-pharmacy-services/advanced-services/smoking-cessation-service/>).
2. From the regional ICB wide eVoucher service: The pharmacy supplies NRT free of charge following the issue of an eVoucher directly to the pharmacy from the maternity Tobacco Dependency Treatment service (<https://www.cpneec.org.uk/locally-commissioned-services/integrated-care-system-services/>).
3. From the local stop smoking service: For example, in County Durham the pharmacy supplies NRT free of charge following the redemption of an e-voucher code on PharmOutcomes (codes supplied to clients by the stop smoking service) (<https://www.cpneec.org.uk/county-durham-services-2/>).

Details of local Stop Smoking Services are available at

- <https://www.freshquit.co.uk/ways-to-quit/local-support/>

For an up-to-date summary of stop smoking medicines:

- See NCSCT website at <https://www.ncsct.co.uk/publications/topCategory/stop-smoking-aids> and <https://www.ncsct.co.uk/publications/stop-smoking-medications-quick-reference>.

Appendix 2: Stop smoking service adviser PharmOutcomes e-recommendation templates to request a pharmacy POM stop smoking medication supply

Template 1: Varenicline client registration template

Client details

- Name
- Address
- Tel number
- DoB
- Name of GP practice

Template 2: Varenicline e-recommendation to pharmacy template

(recommendation to supply template)

Adviser details

- Name
- Contact number
- Stop smoking service
- Local Authority area

Date of issue

Select the pharmacy

Varenicline product requested

Varenicline starter pack

- Week 1-2: varenicline 2-week titration pack (25 tablets (11x0.5mg; 14x1mg).
Dose: Days 1 – 3: 0.5 mg once daily; Days 4 – 7: 0.5 mg twice daily; Day 8 – End of treatment: 1 mg twice daily.

OR

Varenicline 1mg x 28 tablets continuation pack

- Week 3-4: Varenicline 1mg x 28 tablets
- Week 5-6: Varenicline 1mg x 28 tablets
- Week 7-8: Varenicline 1mg x 28 tablets
- Week 9-10: Varenicline 1mg x 28 tablets
- Week 11-12: Varenicline 1mg x 28 tablets

OR

Varenicline 0.5mg x 28 tablets continuation pack

For clients who cannot tolerate the 1mg dose due to e.g. side effects, temporary or permanent dose reduction to:

- Week 3-4: Varenicline 0.5mg x 28 tablets
- Week 5-6: Varenicline 0.5mg x 28 tablets
- Week 7-8: Varenicline 0.5mg x 28 tablets
- Week 9-10: Varenicline 0.5mg x 28 tablets
- Week 11-12: Varenicline 0.5mg x 28 tablets

When Varenicline 2-week starter pack selected (25 tablets):

I can confirm that the client is:

- Aged 18 years and over.
- Tobacco dependent and motivated to quit 7-14 days after starting to take varenicline.

- Receiving behavioural support.
- Not currently pregnant or breast feeding.
- Not aware of any allergies to varenicline or any of its ingredients.
- Not aware of any serious or worrying side effects from a previous course of varenicline.

Client has confirmed no diagnosis of:

- Epilepsy or a history of seizures
- Kidney disease or impairment

Client confirms they are not taking:

- Clozapine, haloperidol or olanzapine (to treat schizophrenia)
- Erlotinib (to treat cancer)
- Riociguat (to treat pulmonary hypertension)
- Theophylline or aminophylline (to treat breathing difficulties)

I need to flag that the client says they:

- Are taking warfarin
- Are using insulin
- Are diagnosed with cardiovascular disease
- Have a history of mental health illness

I have informed the client that:

- NHS prescription charge rules apply to each supply.
- They must visit the pharmacy within 1 week of this referral being sent.
- The pharmacy professional will make the final clinical decision as to whether the supply should be made.
- They must consent to their GP being informed when each supply is made.

When a Varenicline continuation pack is selected (28 tablets):

Select **either** that the previous supply was issued by another service: the template will then ask the same questions as for the starter pack above in order to check that the client is eligible for a continuing supply under this service pathway;
or that the previous supply was issued under this PGD service: the template will ask for confirmation of the following:

I can confirm that the client:

- Has quit smoking.
- Reports no changes to the initial information submitted on inclusion / exclusion criteria.
- Has reported no serious or significant side effects.

I have informed the client that:

- NHS prescription charge rules apply to each supply.
- They must visit the pharmacy within 1 week of this referral being sent.
- The pharmacy professional will make the final clinical decision as to whether the supply should be made.
- They must consent to their GP being informed when each supply is made.

Additional information on the process that the North-East local authority stop smoking service adviser in any setting will follow. The adviser will:

- Agree with the client the community pharmacy that they wish to collect their medication from (using a post-code search for the pharmacies commissioned to provide the service in the North-East region).
- Complete the e-recommendation on PharmOutcomes for varenicline which will be a 2-week supply. This e-recommendation includes basic inclusion and exclusion criteria for the adviser based on this service specification and accompanying PGD.
- Submit the e-recommendation on PharmOutcomes to the client's choice of pharmacy and advise the client to collect the supply within 1 week, that the decision to supply lies with the pharmacy, and that a prescription charge will apply to each supply if the client normally pays for NHS prescriptions.
- Record the drugs requested in the client's record and provide ongoing behavioural support.
- Check the client's PharmOutcomes record within 1 week to check that the supply has been made, or to follow up with the client if the supply has not been made (due to either the client not collecting the medication within 1 week, or the recommended medication not being suitable for that client following the final clinical check by the pharmacy).

Notes:

- The client will be informed that:
 1. The pharmacy will make the final decision as to whether to supply or not and will inform the client's GP practice of a supply.
 2. National guidance dictates that the same NHS prescription charge rules must be applied when medicines are supplied by a prescription or under a PGD.
- For subsequent e-recommendations for varenicline, the client will be encouraged to use the same pharmacy.
- The usual maximum duration of supply requested for varenicline will be 2 weeks. In exceptional cases (e.g. if the client is going on holiday) a slightly longer duration of supply may be requested.
- The client will not be given a copy of the e-recommendation.
- Once the pharmacy has completed the e-recommendation on PharmOutcomes for a client, the stop smoking advisor can then view the outcome of that e-recommendation on PharmOutcomes to determine if the supply has been made or if supply has been rejected and the reasons why.

Appendix 3: Summary of key points in accompanying PGD and copy of the PharmOutcomes GP practice email following each supply of Varenicline

Key points in this service specification and the accompanying PGD

Which clients can access this service?

Criteria for inclusion includes:

- Any client aged 18 years or over who is registered with a North-East general practitioner or resident or working within the North-East and who has had an e-recommendation to supply issued by a participating North-East stop smoking service.

Criteria for exclusion includes:

- Where there are contra-indications to treatment following the clinical assessment as described in the accompanying PGD (and see below).

What treatment options are available?

A 12-week course of varenicline issued as a 2 week supply each time:

- Week 1-2: varenicline 2-week titration pack (25 tablets (11x0.5mg; 14x1mg)).
- Week 3-4: varenicline 1mg x 28 tablets
- Week 5-6: varenicline 1mg x 28 tablets
- Week 7-8: varenicline 1mg x 28 tablets
- Week 9-10: varenicline 1mg x 28 tablets
- Week 11-12: varenicline 1mg x 28 tablets

Note:

- For clients who cannot tolerate the 1mg dose due to e.g. side effects a dose reduction to 0.5mg BD can be made.
- The accompanying PGD does not contain a provision for dose tapering at the end of the 12-week course.

How are quantities entered?

Quantities are entered as the number of tablets and not the number of packs.

Can more than a 2-week supply be requested by the adviser e.g. if the client is going on holiday?

Yes. PharmOutcomes will allow the creation of two separate e-recommendations to the same pharmacy on the same day for the same client. To provide assurance to the pharmacy the adviser is asked to ensure that the week number is correct on each e-recommendation.

Do clients have to pay an NHS prescription charge for each supply?

Yes. National guidance dictates that the same NHS prescription charge rules must be applied when medicines are supplied by a prescription or under a PGD.

What are the key clinical contra-indications and cautions in the PGD?

These are listed below and should be cross-referenced with the PharmOutcomes e-recommendation template that the advisers will use (Appendix 2) and the information that will be emailed to GP practices following each PharmOutcomes supply (see below).

Contra-indications include:

- Previous Stevens-Johnson Syndrome or Erythema Multiforme associated with varenicline use.
- Known or suspected pregnancy (or pregnancy planned during treatment period).
- Currently breastfeeding.
- History of seizures or conditions known to lower the seizure threshold.
- Known or suspected renal disease.

- Individuals taking clozapine or haloperidol or olanzapine; theophylline or aminophylline; erlotinib, and riociguat (see Appendix B in the accompanying PGD).

Cautions include:

Providing the following counselling to clients:

- **Cardiovascular symptoms:** Individuals taking varenicline should be instructed to notify their GP practice of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.
- **Individuals with current or past history of psychiatric disorders:** Individuals should be advised to discontinue varenicline immediately and notify their relevant service provider if they experience serious neuropsychiatric symptoms such as agitation, depressed mood, changes in behaviour or thinking or seek immediate medical advice if they develop suicidal ideation or suicidal behaviour.
- **Stopping smoking can increase the levels of some drugs metabolised by the hepatic enzyme CYP1A2, and hence the dose of these medicines may need to be reduced** (<https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/>):
 1. Patients taking warfarin should be advised to inform their anticoagulation clinic and to discuss the need for more frequent testing.
 2. Patients using insulin should be advised to monitor their blood glucose more frequently during their quit attempt.
 3. Patients taking agomelatine, chlorpromazine, flecainide, fluvoxamine, methadone, mexiletine, melatonin, riluzole or ropinirole should be advised of the risk of increased adverse effects with these drugs when stopping smoking and should be advised to speak to their prescriber should this occur.

How quickly should the PharmOutcomes supply template be completed?

Please ensure that this template is completed within 1 day of supply. This is particularly important for the supply of the starter pack, in order to inform the GP practice 1 week before a client quit attempt, so that the GP practice has sufficient time to raise any concerns with the pharmacy.

What happens if the GP practice raises concerns with the pharmacy about varenicline supply?

The pharmacy should directly notify the stop smoking service adviser if concerns on the supply of varenicline are received back from the GP practice. The adviser's contact details will be available in the e-recommendation which can be viewed in completed consultations.

Does the pharmacy have the option of rejecting an e-recommendation?

Yes. The e-recommendation can be rejected if the client either has not attended the pharmacy to collect their medication within 1 week of the e-recommendation being received or the registered pharmacy healthcare professional has assessed the client as being unsuitable for the requested medication.

What information will be sent to the client's GP practice?

Completion of each supply on PharmOutcomes by the pharmacy will automatically send an email to the client's GP practice. This will state:

Notification of supply of varenicline

Client's details:

Your patient has been assessed as being suitable for varenicline as part of their current quit attempt with the local stop smoking service (contact details at <https://www.freshquit.co.uk/ways-to-quit/local-support/>).

I have ascertained that your patient does not have any contra-indications for taking varenicline and meets the criteria for a supply under a regional patient group direction.

On clinical assessment, your patient has advised:

- No history of epilepsy, seizures or other conditions which may potentially lower the seizure threshold.
- No known renal impairment.
- They are not pregnant or breastfeeding (as applicable).
- That they are not prescribed any of the following drugs: clozapine, erlotinib, haloperidol, olanzapine, riociguat, theophylline or aminophylline.

Patients are advised:

- To seek medical advice for any new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of heart attack or stroke.
- To discontinue medication and seek medical advice if they experience serious psychiatric symptoms such as depressed mood, agitation, changes in behaviour or thinking and to seek immediate medical advice if they develop suicide thoughts or behaviour.
- To discontinue medication and seek immediate medical advice if they develop an allergic reaction (e.g. angioedema) and/or skin reactions (e.g. Stevens Johnson syndrome).
- That varenicline may cause dizziness, drowsiness and temporary loss of consciousness and therefore may influence the ability to drive and use machines.
- That the very common side effects at the beginning of treatment include nausea, headaches and difficulty sleeping.

Stopping smoking can increase the levels of some drugs metabolised by the hepatic enzyme CYP1A2, and hence the dose of these medicines may need to be reduced

(<https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/>):

- Patients taking warfarin have been advised to inform their anticoagulation clinic and to discuss the need for more frequent testing.
- Patients using insulin have been advised to monitor their blood glucose more frequently during their quit attempt.
- Patients taking agomelatine, chlorpromazine, flecainide, fluvoxamine, methadone, mexiletine, melatonin, riluzole or ropinirole have been advised of the risk of increased adverse effects with these drugs when stopping smoking and have been advised to speak to their prescriber should this occur.

If you have any concerns about this patient taking varenicline, please do not hesitate to contact the pharmacy.

Appendix 4: PharmOutcomes Declaration

Your full name

Your registration number

I confirm that I:

- Am competent to work under a PGD
- Have read, signed and understand the PGD for varenicline provision
- Have read and understand the SLA for varenicline provision