



PATIENT GROUP DIRECTION (PGD)

NICOTINE REPLACEMENT
THERAPY PRODUCTS (NRT) FOR PHARMACIES DELIVERING BEHAVIOURAL
SUPPORT FOR STOP SMOKING UNDER A PUBLIC HEALTH ENHANCED SERVICE
(PHES) CONTRACT

 Developed in partnership with Gloucestershire County Council

Documentation details


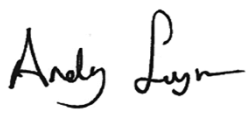


Reference no:	PGD NRT May 2021
Version no:	2021-2023 v1
Valid from:	1/7/2021
Review date:	May 2023
Expiry date:	30/06/2023

Change history

Version number	Change details	Date
2021 - 2023 v1	<ul style="list-style-type: none"> Format change to be compliant with National PGD template Authorisation pages 2 and 12 to be sent electronically instead of posted to Tracy Marshall 	May 2021
2019-2021 v3	<ul style="list-style-type: none"> Minor changes to professional body information, text and hyperlinks. Removal of references to practice nurses 	1.6.19
2017 - 2019	<ul style="list-style-type: none"> Updated ; Change in provider; addition oral strip product, removal of provision for pregnant women via this PGD 	1.7.17
2015 - 2017	<ul style="list-style-type: none"> Reviewed /updated – Reworded around training of NRT with regard to supply during pregnancy 	1.7.15

1. PGD development

This PGD has been developed by the following health professionals on behalf of NHS Gloucestershire Clinical Commissioning Group (GCCG):

Developed by:	Name	Signature	Date
Pharmacist	NHS Gloucestershire CCG Deputy Director of Quality Teresa Middleton		06.07.2021
Doctor	NHS Gloucestershire CCG Clinical Chair Dr Andrew Seymour		06.07.2021
Nurse	NHS Gloucestershire CCG Executive Nurse and Quality Lead Dr Marion Andrews-Evans		28.06.2021
Public Health	Executive Director of Adult Social Care and Public Health Gloucestershire County Council Sarah Scott		07.07.2021
To Pharmacy Contractor Please ensure this is signed by appropriate pharmacist and send a scanned copy of this page and page 12 to; <i>Tracy Marshall</i> Tracy.marshall@goucestershire.gov.uk	Clinical Governance Pharmacist (for the Pharmacy) Name (print)		

This document has been written and authorised on the understanding that it remains in its entirety with no additions, omissions or alterations.

All information contained within this document was correct at the time of going to press. It is acknowledged that systems and processes change over time and that new drugs may be introduced. As licences vary, if a new brand is introduced it will not necessarily be covered within its corresponding PGD. If there are changes to practice, or the need for more PGDs to be developed, please contact the Head of Medicine Management at NHS Gloucestershire Clinical Commissioning Group (CCG).

This PGD has been peer reviewed by the GCCG PGD Working Group

PGD Working Group Membership

Name	Designation
Teresa Middleton	NHS Gloucestershire CCG Deputy Director of Quality
Andrew Seymour	NHS Gloucestershire CCG Clinical Chair
Marion Andrews-Evans	NHS Gloucestershire CCG Executive Nurse and Quality Lead
Julie Symonds	NHS Gloucestershire CCG Deputy Director of Nursing
Helen Acock	NHS Gloucestershire CCG Clinical Learning and Development Matron
Sarah Scott	Executive Director of Adult Social Care and Public Health Gloucestershire County Council
Liz Ponting	NHS Gloucestershire CCG Senior Medicines Optimisation Pharmacist

Additional Advice From	
Tracy Marshall	Gloucestershire County Council Outcome Manager (Public Health)
Nicki Blyth	Gloucestershire Healthy Lifestyles Training Lead and Smoking Cessation Specialist

2. Organisational authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Gloucestershire County Council/NHS Gloucestershire Clinical Commissioning Group
authorises this PGD for use by the services or providers listed below:
Practitioners who are: <ul style="list-style-type: none">Contracted through a current signed Service Specification with Gloucestershire County
Limitations to authorisation
<ul style="list-style-type: none">This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it.The most recent in-date final version authorised by Gloucestershire County Council and NHS Gloucestershire Clinical Commissioning Group must be used.

To Pharmacy Contractor

Please ensure the organisational approval section is signed by the appropriate pharmacist and that they **email a scanned** copy of the completed page 2 and a completed copy of Section 7 (page 12) to Tracy Marshall – Tracy.marshall@gloucestershire.gov.uk

All pharmacies should retain a 'fully signed' copy (completed pages 2 and 12) of the PGD for their files and/or this should be sent on to the head of service for their reference.

Any concerns regarding the content of this PGD should be addressed to: glccg.medicines@nhs.net

3. Characteristics of staff

Qualifications and professional registration	<p>Registered Professional legally able to work under a PGD E.g. Pharmacist registered as a practising pharmacist with GPhC GB.</p> <p>All practitioners must be:</p> <ul style="list-style-type: none"> Contracted under a Public Health Enhanced Service (PHES) contract with Gloucestershire County Council
Initial training	<p>All practitioners must have read and understood, and act in accordance with (as appropriate):</p> <ul style="list-style-type: none"> Medicines Healthcare products Regulation Agency Guidance Patient Group Directions and who can use them Current GPhC Standards for pharmacy professionals <p>In addition practitioners must have:</p> <ul style="list-style-type: none"> Completed PGD training – they must attend an update provided by HLS Glos. at least once every 2 years plus self-directed. https://www.nice.org.uk/guidance/mpg2 Competency framework for health professionals using patient group directions https://www.cppe.ac.uk/ All professionals delivering stop smoking behavioural support must have completed the appropriate training programme delivered by Gloucestershire Healthy Lifestyles Service The NRT Adviser must also have completed and achieved full 'National Centre for Smoking Cessation and Training (NCSCT) certification status (Assessment of core knowledge and key practice skills) provided via the Centre for Pharmacy Postgraduate Education (CPPE) website and be prepared to accept this delegated role https://www.cppe.ac.uk Signed the signature sheet for the PGD Been assessed as competent by their line manager
Competency assessment	<p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.</p>
Ongoing training and competency	<p>Mandatory Additional Training</p> <ul style="list-style-type: none"> Keep up-to-date with changes to recommendations for medicines covered by this PGD Review of competency and any training requirements with manager at least annually

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Adults and children from 12 years of age, who are seeking support to quit smoking.
Criteria for inclusion	<ul style="list-style-type: none"> • Adults and children over 12 years of age who have presented at a Community Pharmacy, and who are deemed sufficiently motivated to quit and who agree to enter the support programme. <p>NOTE – see exclusions if woman is pregnant NOTE – see cautions if breastfeeding NOTE – see cautions if history of gastritis oesophagitis or peptic ulcers</p>
Criteria for exclusion	<ul style="list-style-type: none"> • No valid consent • Person's lack of commitment to the support programme • Current use of Bupropion (Zyban) • Current use of Varenicline (Champix) • Pregnant women • Previous allergic reaction to an NRT product • Unstable Cardiovascular disease (unless approved by hospital consultant – see referral arrangements) • Stroke in the previous 2 weeks (unless approved by GP – see referral arrangements) • Uncontrolled hyperthyroidism or phaeochromocytoma • Chronic generalised skin disease (patches only) • Chronic nasal disorder (nasal spray only) • Phenylketonuria (lozenges only) • People who have been unsuccessful with the service in the last six months, unless deemed ready for another attempt by the Smoking Cessation Adviser • Hypersensitivity to any of the ingredients contained within the product • Under 12 years of age.
Cautions including any relevant action to be taken	<p><u>General</u></p> <ul style="list-style-type: none"> • Diabetes – Diabetics will need to monitor their blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism. • Gastrointestinal problems may be exacerbated if using oral NRT preparations. • Caution in people with severe renal impairment. • Caution in people with moderate or severe hepatic impairment. • People who have suffered from any gastritis, oesophagitis or peptic ulcers should be encouraged to stop smoking without the use of NRT. (See side-effects). If they still feel they need NRT then use NRT patches. If using oral products ensure correct use, as swallowing nicotine could cause increased gastric problems. <p><u>Pregnancy:</u></p> <ul style="list-style-type: none"> • Pregnant smokers see exclusion criteria • Pregnant smokers wishing to stop smoking should be referred to the Healthy Lifestyles Service who can provide specialist advice and support <p style="text-align: right;">Continued</p>

<p>Cautions including any relevant action to be taken (continued)</p>	<p><u>Breastfeeding:</u> Under this PGD NRT may be supplied to breastfeeding women as long as:</p> <ul style="list-style-type: none"> • The woman understands the risks and benefits • For lactating mothers an oral product is recommended in the first instance. It is important to discuss the timing of NRT use during the day (i.e. after a breast feed and two hours prior to a feed). <p>However, if the client will find it difficult to remain abstinent on an oral product, the risk benefit ratio of smoking compared to longer lasting NRT should be taken into account’.</p> <p><u>Drug interactions:</u> Smoking cessation may cause alteration to drug levels in the patients taking the following drugs. This would not normally be sufficient to cause therapeutic problems but clients should ensure their GP is aware that they are attempting to quit.</p> <ul style="list-style-type: none"> • Insulin • Beta agonists • Beta blockers • Alpha blockers • Oxazepam • Furosemide • H2 receptor antagonists • Warfarin • Fluvoxamine • Clomipramine • Imipramine • Olanzapine • Flecainide • Tacrine • Pentazocine • Theophylline • Cinacalcet, • Ropinirole • Some antipsychotics (including clozapine, olanzapine, chlorpromazine and haloperidol)
<p>Action to be taken if the patient is excluded</p>	<ul style="list-style-type: none"> • If person is excluded, refer to his or her own GP or Healthy Lifestyle Service (Phone: 0800 122 3788 or email: info@hlsqlos.org)
<p>Action to be taken if the patient or carer declines treatment</p>	<p>If person refuses to participate in programme:</p> <ul style="list-style-type: none"> • Ensure they understand the benefits of the programme • Make them aware of the statistics for success rates of those following the programme compared with those who do not • Tell them NRT is available to buy if they wish to attempt to quit without involvement in the programme • Make sure they keep a note of contact telephone numbers if they decide to participate in the programme in the future.

Arrangements for referral for medical advice	<ul style="list-style-type: none"> • People for whom Bupropion (Zyban) or Varenicline (Champix) is more appropriate should be referred to their GP for a prescription <p>People who would normally be excluded due to unstable Cardiovascular disease, Recent Stroke (within the previous two week) may receive treatment under this PGD as long as:</p> <ul style="list-style-type: none"> • They have been referred to their GP for the initial prescription and the GP has consented to the adviser continuing the treatment under the PGD. • The person has consented to the GP being approached by the adviser.
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5. Description of treatment

Name, strength & formulation of drug	<p>Nicotine Replacement Therapy (NRT) NRT may be supplied in one or more of the following forms:</p> <ul style="list-style-type: none"> • transdermal patches • chewing gum • lozenges • inhalator • nasal spray • micro tabs/sublingual tablets • oromucosal spray <p>Please see Section 6 below on page 11 which includes a list of current products and strengths available Strengths vary depending on dosage form.</p>
Legal category	General Sale List (GSL)
Route / method of administration	Oral, transdermal, nasal or inhaled, according to the product.
Indicate any off-label use	N/A
Dose and frequency of administration	<ul style="list-style-type: none"> • Dosage to be determined by the smoking cessation adviser in line with the recommendations of the product supplied. Dosage should be informed by the time to first cigarette and Carbon Monoxide (CO) reading when possible to perform • The supply of product given to the person at each consultation will be in line with his/her requirement, until the next consultation, which will usually be one or two weeks supply, then review • The total number of week's supply of NRT product given to anyone will be based on the individual's need up to a maximum of 12 weeks. • Compliance should be confirmed through the use of Carbon Monoxide (CO) readings.
Duration of treatment	The total number of week's supply of NRT product given to anyone will be based on the individual's need up to a maximum of 12 weeks
Quantity to be supplied	The supply of product given to the person at each consultation will be in line with his/her requirement, until the next consultation, which will usually one or two weeks supply at a time, then review
Storage	<ul style="list-style-type: none"> • Products should be stored below 25°C.

Drug interactions	<p>Smoking cessation may cause alteration to drug levels in the patients taking the following drugs. This would not normally be sufficient to cause therapeutic problems but clients should ensure their GP is aware that they are attempting to quit.</p> <ul style="list-style-type: none"> • Insulin • Beta agonists • Beta blockers • Alpha blockers • Oxazepam • Furosemide • H2 receptor antagonists • Warfarin • Fluvoxamine • Clomipramine • Imipramine • Olanzapine • Flecainide • Tacrine • Pentazocine • Theophylline • Cinacalcet, • Ropinirole • Some antipsychotics (including clozapine, olanzapine, chlorpromazine and haloperidol)
Identification & management of adverse reactions	<p>Adverse reactions are usually transient and may be due to either the NRT or the cessation of smoking. Side effects may include: Gastro-intestinal disturbances (including nausea, vomiting and dyspepsia); headache, dizziness, cold/flu-like illness, dry mouth, rash. Less frequently: palpitations, Rarely: atrial fibrillation</p> <p><i>With nasal spray:</i> sneezing, epistaxis, watering eyes, ear sensations. <i>With lozenge:</i> thirst, paraesthesia of mouth, taste disturbance. <i>With patches:</i> skin reactions –discontinue if severe, vasculitis reported and changes in blood pressure <i>With patches or lozenge:</i> sleep disturbances, nightmares, chest pain. <i>With gum, lozenge or oral film/strip:</i> mouth ulceration, increased salivation. <i>With gum, lozenge, sublingual tablet or inhalator:</i> hiccups, throat irritation <i>With oromucosal spray:</i> hiccups, oral symptoms such as burning lips or taste disturbance and gastric upset</p> <p>See Summary of Product Characteristics for full list for each product.</p>
Management of and reporting procedure for adverse reactions	<p>If an adverse reaction occurs:</p> <ul style="list-style-type: none"> • Stop treatment • Inform person's GP as soon as possible • Document details • Discuss with GP the need to report the reaction to the MHRA (Medicines & Healthcare Products Regulatory Agency), using the yellow card system via the following link: http://yellowcard.mhra.gov.uk/ <p style="text-align: right;">Continued</p>

	<p>Note: specific adverse reactions may be listed for each individual drug, see Summary of Product Characteristics for full list for each product.</p>
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	<p>People should be given advice on:</p> <ul style="list-style-type: none"> • Withdrawal symptoms • Possible weight gain • Effects of caffeine may be enhanced • Effects of smoking while using NRT • Self-help groups • Information leaflets • Support-line telephone numbers • Follow-up information
Records	<p>A record of supply should be made on patient medication record. This should include:</p> <ul style="list-style-type: none"> • Start date and quit date • Date of supply • Name and address and date of birth • Product supplied • Quantity supplied • Dose • Frequency • Batch number and expiry date • Advice given, oral or written • Contra-indications and medical advice • Signature of supplier, or record on computer using individual-protected password • Date of next consultation • Invoices • Prescription charges collected • Claim for payment via PharmOutcomes • Record of attempts to contact those lost to follow-up. At least two attempts must be made by the Smoking Cessation Adviser. <p>Any requested audit forms should be completed and returned as requested to Gloucestershire County Council Patients who refuse to participate should have the refusal recorded.</p> <p>A computer or manual record of all individuals receiving NRT under this Direction should also be kept for audit purposes within each organisation using it.</p>
Consent	<ul style="list-style-type: none"> • Written consent or documented verbal consent must be obtained before treatment is provided. All people must agree to the terms of the supply of NRT products, including the participation in the support programme, sharing information with their GP, and inclusion in GCC / NHS Gloucestershire data. • Those under 12 years old should be referred to his/her GP. <p>For consent to be valid, the patient must</p> <ul style="list-style-type: none"> • be competent to take the particular decision • have received sufficient information to take it • not be acting under duress

Continued

	<p>Anyone aged 18 years or over is assumed to be capable of making decisions unless there is reasonable doubt that they lack capacity.</p> <p>Anyone aged 16 to 17 years (young person) is also assumed to be capable of making decisions unless there is reasonable doubt that they lack capacity.</p> <p>Children under the age of 16 can consent to their own treatment if they are believed to have enough intelligence, competence and understanding to fully appreciate what is involved in their treatment.</p> <p>For further guidance please refer to Department of Health document consent for examination or treatment (second edition) DH 2009. Gateway reference 11911 or GPhC guidance on consent</p>
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6. Key references and list of NRT products available

Key references	<ul style="list-style-type: none"> • BNF – latest online version • Guidance Patient group directions: who can use them Updated 4 December 2017 • NHS Exec. Patient Group Directions (England only). HSC 2000/026. Leeds: NHSE, 2000 (web archive) • http://www.druginfozone.nhs.uk • Summary of Product Characteristics (SPC) • GPhC Standards for pharmacy professionals • http://www.nice.org.uk • Guidance on Prescribing, Dispensing, Supplying and Administration of Medicines March 2020 RCN and RPharmS • Guidance on Prescribing, Dispensing, Supplying and Administration of Medicines March 2020 RCN and RPharmS • http://www.nice.org.uk/mpc/medicinespracticeguidelines/mpg2.jsp • https://www.cppe.ac.uk • CQC (2016) <i>Nigel's surgery 8: Gillick competency and Fraser guidelines</i> http://www.cqc.org.uk/content/nigels-surgery-8-gillick-competency-and-fraser-guidelines • DH (2009) Reference guide to consent for examination or treatment (2nd ed.) • MHRA Yellow card
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List of NRT PRODUCTS AVAILABLE
(See current BNF or SPC for recommended doses)

TYPE	STRENGTH	BRAND
Gum	2mg; 4mg;	Nicorette (mint, freshfruit, freshmint & icy white) NiQuitin (mint) Nicotinell (fruit, mint, liquorice & icemint) NicAssist
Transdermal Patch	15mg/16 hours; 10mg/16 hours; 5mg/16 hours	Nicorette Nicorette Invisi NicAssist (Boots) NicAssist translucent
Transdermal Patch	21mg/24 hours; 14mg/24 hours; 7mg/24 hours	Nicotinell TTS NiQuitin CQ NiQuitin CQ Clear Nicopatch
Lozenge	1mg; 1.5mg (as reinate); 2mg; 4mg	Nicotinell (1mg, 2mg) NiQuitin (2mg, 4mg) NiQuitin minis/NiQuitin Pre-quit (1.5mg cherry & mint) Nicorette (2mg)
Microtabs	2mg	Nicorette NicAssist (Boots)
Inhalator	15mg/cartridge	Nicorette NicAssist (Boots)
Nasal Spray	500micrograms per metered spray	Nicorette NicAssist (Boots)
Oromucosal Spray	1mg per spray - mouth spray	Nicorette Quickmist

7. List of Accredited Pharmacists working under the PGD at the pharmacy premises below who have a Public Health Enhanced Service (PHES) contract to work under the Patient Group Direction for Nicotine Replacement Therapy.

Name of Pharmacist (print)	GPhC registration number	Date of attendance of training by HLS Glos or CPPE/NCSCT	Signature

Name and Address of Premises:

To Pharmacy Contractor:

- Please retain one completed copy of this page for your files.
- Please email one scanned copy of this completed page with a scan of the signed authorisation in Section 1 (page 2) (i.e. email scanned copies of page 2 and 12):

To Tracy Marshall – Tracy.marshall@gloucestershire.gov.uk