GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Protocol must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the Protocol should be used. Health professionals should always access the Protocol via the PTHB internet to ensure that they are always working to the most up to date version

Protocol

for the supply of

Nicotine replacement therapy (NRT)

to individuals

to relieve and/or prevent craving and nicotine withdrawal symptoms whilst unable to smoke or vape on hospital grounds

by registered health professionals working in Powys Teaching Health Board

Document Reference No:	PTHB / MMP 453	
Version No:	1	
Issue Date:	20/08/2024	
Review Date:	20/08/2026	
Author:	Clinical Pharmacist	
Document Owner:	Chief Pharmacist	
Accountable Executive:	Medical Director	
Approved By:	Area Prescribing Group	
Approval Date:	20/06/2024	
Document Type:	Protocol	Clinical
Scope:	Authorised registered nurses, midwives, pharmacists and pharmacy technicians in PTHB	

Do not print this document. The latest version will be accessible via the internet. If the review date has passed, please contact the Author for advice.

Change history

Version number	Change details	Date
MMP 453	New protocol	20/08/2024

For advice on protocol use in practice and advised supporting governance please refer to When Patient Group Directions are not required.

This protocol was developed to support approved staff in Powys Teaching Health Board to supply the following NRT products: NiQuitin Clear patch 21mg/24 hours, Nicorette 15mg inhalator, Nicorette QuickMist 1mg, Nicorette fruit lozenge 2mg and Nicorette Cools lozenge 4mg, to assist smokers who are unable to smoke, by relieving and/or preventing craving and nicotine withdrawal symptoms**.**

Although the nicotine withdrawal effects of vaping cessation have not been established, it is anticipated that many of the effects relating to nicotine withdrawal will be the same as those seen with tobacco smoking cessation. Nicorette QuickMist 1mg is licensed, and approved under this protocol, to assist vapers who are unable to vape, by relieving and/or preventing craving and nicotine withdrawal symptoms**.**

Note: packs supplied under this protocol must be original, sealed General Sales List (GSL) packs only.

Product selection is in line with the AWMSG guidance Initial Clinical Management of Adult smokers in secondary care and the PTHB formulary.

This protocol has been developed to support staff to ensure that an individual will be able to receive NRT within 4 hours of admission (if requested and appropriate) in order to manage their nicotine withdrawal symptoms, as recommended in the AWMSG guidance Initial Clinical Management of Adult smokers in secondary care.

Protocol authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	8/20/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	Signed by: Jacqui Seaton 71E8089DE3634C4...	8/27/2024
Senior representative of professional group using the Protocol **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	8/27/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	8/27/2024

Appendix A provides a competency checklist and a 'Staff permitted to use Protocol' Signature Sheet. Individual practitioners must be authorised by name to work to this Protocol.

The final authorised copy of this Protocol should be kept by Powys Teaching Health Board (PTHB) for 25 years after the Protocol expires.

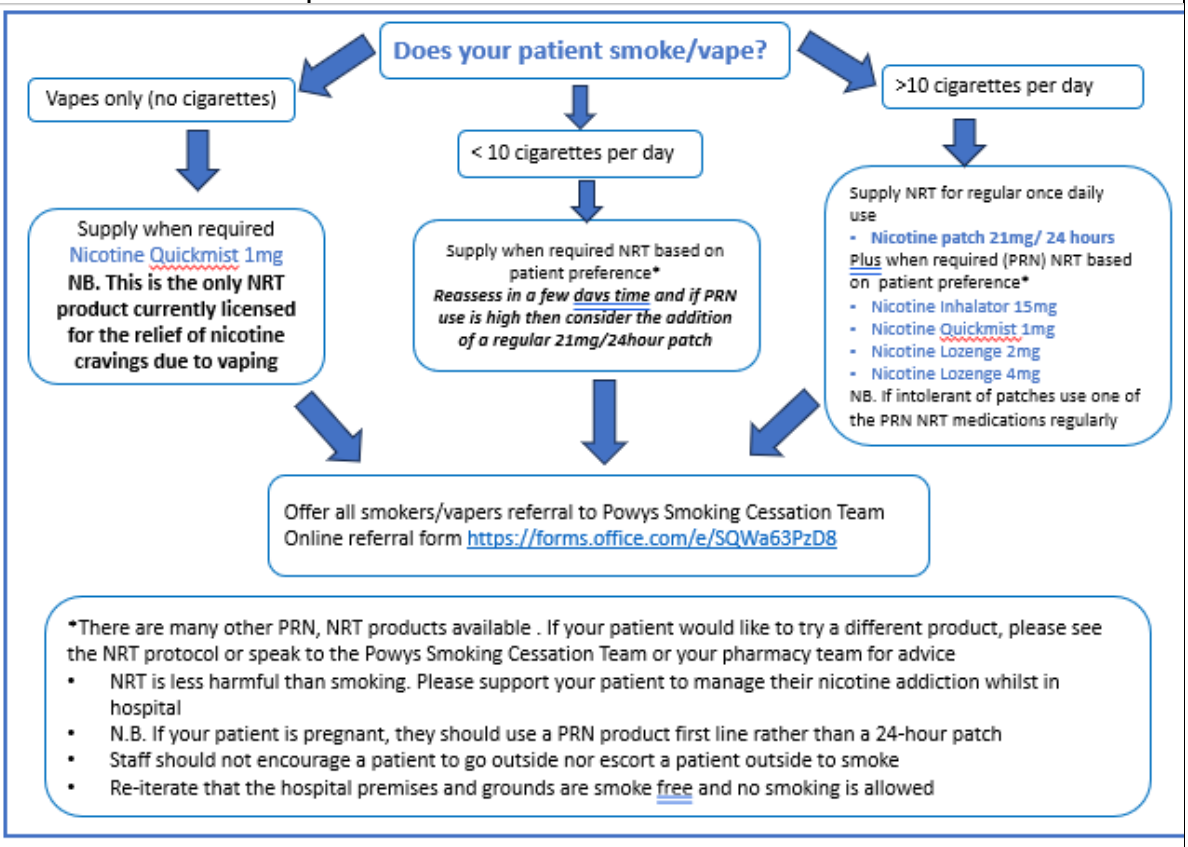
Competencies of staff	
Qualifications and professional registration	Practitioners must only work under this Protocol where they are competent to do so, and are a registered professional with one of the following bodies: • nurses and/or midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists registered with the GPhC • pharmacy technicians registered with the GPhC All registered health professionals should have a current contract of employment with Powys Teaching Health Board. The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff permitted to use the Protocol to confirm whether all practitioners listed above have organisational authorisation to work under this Protocol.
Initial training	• The supply of NRT and knowledge of the uses, contraindications and adverse effects. • Be alert to changes in the BNF/ Summary of Product Characteristics • Must be competent to assess the individual's need for NRT. • NCSCT Online Smoking Cessation Training which can be accessed via: http://elearning.ncsct.co.uk/wales. • Must be competent to discuss the treatment to be supplied with the individual/carer and obtain consent. • Must be competent to assess mental capacity and follow the Mental Capacity Act 2005 guidance regarding consent to treatment. • Must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills (as a minimum).

	• Must be competent to record the assessment, any intervention and arrangement for review in the nursing notes, care plan or care pathway. • Must be authorised by name as an approved practitioner under the current terms of this protocol before working to it • Must have undertaken appropriate training for working under protocols for administration/ supply of medicines (Team leaders may access 'Protocol and guideline awareness training' by sending a request to info.medicinesmanagement.powys@wales.nhs.uk; the team leader will then train their team) • Must have access to the protocol and associated online resources • Must have undertaken and completed Safeguarding of Children, Young people and Vulnerable adults – Training and Competency passport, as applicable to the role **THE DECISION TO SUPPLY ANY MEDICATION RESTS WITH THE INDIVIDUAL PRACTITIONER WHO MUST ABIDE BY THE PROTOCOL AND ANY ASSOCIATED ORGANISATION POLICIES.**
Competency assessment	Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Individuals operating under this Protocol must be assessed as competent (see Appendix A), this should be recorded using the competency checklist in Appendix A. Practitioners must make a self-declaration of competency in their PADR– the **personal development plan** (yellow) section of the PADR booklet should be used to record completion of annual protocol training. ESR records of mandatory NHS training.
Ongoing training and competency	Updating at least annually on the use of NRT. Practitioners should be constantly alert to any sources of medicines information.

	Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, a minimum of Basic Life Support Skills, safeguarding, with evidence of appropriate Continued Professional Development (CPD). Compliance with all mandatory NHS training. **It is the responsibility of the healthcare practitioner to maintain their own competency to practice within this Protocol.**
Arrangements for referral for medical advice	Record reason, contact medical team and document advice given.
Action to be taken if individual excluded	Individuals will immediately be brought to the attention of an appropriate medical or non-medical prescriber, record reason for exclusion and any action taken. Explain reason to individual / carer.
Action to be taken if individual declines treatment	Explain consequences of refusing treatment. Record reason for decline, advice given and any action taken in the consultation record. Follow local procedures as appropriate.

Clinical condition or situation to which this protocol applies

Nicotine Replacement Therapy (NRT) relieves and/or prevents cravings and nicotine withdrawal symptoms associated with tobacco dependence. Its indications include assisting smokers who are unable to smoke, such as on hospital grounds where smoking is illegal, and as a safer alternative to smoking for smokers and those around them. The protocol must only be used for individuals who are not already using pharmacotherapy for smoking cessation, in which case a prescriber should continue to prescribe.



NB. If the individual is breast feeding, intermittent therapy is preferred.

Prescribing information varies for each specific NRT product contained in the protocol – take care to refer to the relevant section. The inclusion, exclusion criteria and cautions for the specific product MUST be checked, in addition to the general cautions for NRT.

Nicorette QuickMist 1mg is also licensed to assist vapers who are unable to vape.

It is the responsibility of the supplying healthcare practitioner to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the supply. If there is any reason for concern, seek medical advice.

General cautions for all medicines in this protocol:	
General cautions/reasons for seeking further advice from a prescriber	• Diabetes mellitus: blood-glucose concentration should be monitored closely when initiating treatment • Haemodynamically unstable individuals hospitalised with cerebrovascular accident, myocardial infarction or severe arrhythmias, or with unstable or worsening angina (including Prinzmetal's angina) and/or who have uncontrolled hypertension should be encouraged to stop smoking with non-pharmacological interventions. If this fails, NRT may be considered, but initiation should only be under medical supervision. • Phaeochromocytoma • Uncontrolled hyperthyroidism • Most warnings for nicotine replacement therapy also apply to continued cigarette smoking, but the risk of continued smoking outweighs any risks of using nicotine preparations. The risks of continued vaping are not yet established. • Hepatic impairment: Manufacturer advises caution in moderate to severe impairment (risk of decreased clearance). • Severe renal impairment • Seizures: Potential risks and benefits of nicotine should be carefully evaluated before use in subjects taking anti-convulsant therapy or with a history of epilepsy as cases of convulsions have been reported in association with nicotine. • Nicotine replacement therapy may exacerbate symptoms in persons suffering from active oesophagitis, oral and pharyngeal inflammation, gastritis, gastric ulcer or peptic ulcer • Allergic reactions- susceptibility to angioedema and urticaria

General cautions/reasons for seeking further advice from a prescriber	• Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or MHRA Products | Home • Individuals with complex multiple pathologies, polypharmacy or multiple allergies. • Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed, where appropriate. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads

Drug Interactions	• When a smoker stops smoking, there may be slower metabolism and a rise in blood levels of certain drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, clozapine and ropinirole. • No clinically relevant interactions between nicotine replacement therapy and other drugs have definitely been established. However, nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.
Storage	Medicines must be stored securely according to national guidelines. Refer to product SPC via www.medicines.org.uk or MHRA Products | Home for the specific product
Details of the Specific Products NiQuitin Clear patch 21mg/24 hours Nicorette 15mg inhalator Nicorette QuickMist 1mg Nicorette fruit lozenge 2mg Nicorette Cools lozenge 4mg	

Details of the medicine: NiQuitin Clear Patch ® 21mg/24hours	
Name, form and strength	NiQuitin Clear Patch ® 21mg/24hours 114 mg nicotine, equivalent to 5.1 mg/cm^2 of nicotine and delivers 21 mg over 24 hours
NiQuitin Clear Patch ® 21mg/24hours: Inclusion criteria	• Informed consent obtained. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion • Individual who smokes 10 or more cigarettes per day, requiring NRT • Individuals 12 years and over • In case of any doubt, contact medical team
NiQuitin Clear Patch ® 21mg/24hours: Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the individual is excluded" and "action to be taken if the individual declines treatment". • Hypersensitivity or allergy to any of the ingredients or excipients of the preparation (see SPC MHRA Products | Home) • Individuals under 12 years. • Occasional smokers and non-smokers. • Individual who has been assessed by a clinician and deemed NRT inappropriate
NiQuitin Clear Patch ® 21mg/24hours: Cautions/reasons for seeking further advice from a prescriber	• Individuals with skin disorders • NiQuitin Clear is potentially a dermal irritant and can cause contact sensitisation: Individuals with contact sensitisation should be cautioned that a serious reaction could occur from exposure to other nicotine-containing products or smoking. • Atopic or eczematous dermatitis (due to localised patch sensitivity): In the case of severe or persistent local

	reactions at the site of application (e.g. severe erythema, pruritus or oedema) or a generalised skin reaction (e.g. urticaria, hives or generalised skin rashes), users should be instructed to discontinue use of NiQuitin and contact their physician • Patches should not be placed on red, broken or irritated skin • Breastfeeding - intermittent therapy is preferred • Also see General cautions
NiQuitin Clear Patch ® 21mg/24hours: Route/method of administration	Topical. Remove old patch before applying a new one. Remove protective liner from patch immediately prior to use. Patch should be applied to clean, dry, non-hairy skin on the hip, trunk, or upper arm and held in position for 10–20 seconds to ensure adhesion; place next patch on a different area and avoid using the same site for at least 7 days. Areas where the skin creases should be avoided. Patches should not be placed on red, irritated or broken skin. The user should wash hands with water alone (no soap, which may increase nicotine absorption) after handling the patch, and avoid contact with eyes and nose.
NiQuitin Clear Patch ® 21mg/24hours: Dose and frequency	One patch to be applied once daily, at the same time each day and preferably soon after waking. Patch is usually worn continuously for 24 hours (to optimise the effect against morning cravings), however, patch may be removed before going to bed if desired, for example, if

	individual is experiencing sleep disturbance or nightmares. NB. If patches are used during pregnancy, the patch should be removed at night before going to bed.
NiQuitin Clear Patch ® 21mg/24hours: Max duration of treatment via protocol	Maximum quantity to be supplied is one pack of 7 per week. Individual to be reviewed by a clinician at the next available opportunity. If users are still feeling the need to use the patches on a regular basis 6 months after the start of treatment, then it is recommended to seek additional help and advice from a healthcare professional. Individuals who have decided NOT to start a quit attempt and have been treated with NRT for nicotine withdrawal only will NOT receive a supply on discharge.

Details of the medicine: Nicorette ® 15mg Inhalator	
Name, form and strength	Nicorette ® 15mg Inhalator (nicotine cartridge for inhalation, as a complete pack of 4 cartridges with an inhalator device) Nicotine 15mg per cartridge
Nicorette ® 15mg Inhalator: Inclusion criteria	• Informed consent obtained. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion • Individuals 12 years and over • Individual requiring NRT, whenever the urge to smoke is felt or to prevent cravings. • In case of any doubt, contact medical team
Nicorette ® 15mg Inhalator: Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the individual is excluded" and "action to be taken if the individual declines treatment". • Hypersensitivity or allergy to any of the ingredients or excipients of the preparation (see SPC www.medicines.org.uk) • Individuals with known hypersensitivity to levomenthol or polyethylene • Individuals under 12 years • Non-smokers • Individual who has been assessed by a clinician and deemed NRT inappropriate
Nicorette ® 15mg Inhalator: Cautions/reasons for seeking further advice from a prescriber	• Bronchospastic disease • Chronic throat disease • Obstructive lung disease- individuals may find use of the inhalator difficult • Also see General cautions

Nicorette ® 15mg Inhalator: Route/method of administration	Insert the cartridge into the device (according to the instructions) and draw in air through the mouthpiece; each cartridge can be used for approximately eight 5-minute sessions, with each cartridge lasting approximately 40 minutes of intense use. The amount of nicotine from 1 puff of the cartridge is less than that from a cigarette, therefore it is necessary to inhale more often than when smoking a cigarette. Potential choking hazard: This product contains some small parts. Any unused cartridges should never be thrown away or left lying around – they should be kept in the cartridge tray to minimise the risk of swallowing, and disposed of with household rubbish. Once inserted into the mouthpiece the cartridge should be disposed of within 48 hours even if it has not been used.
Nicorette ® 15mg Inhalator: Dose and frequency	The cartridge may be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. The amount of nicotine from a puff is less than that from a cigarette. To compensate for less nicotine delivery from a puff it is necessary to inhale more often than when smoking a cigarette. This product works best at room temperature. In cold conditions (below 15°C) the nicotine evaporates less readily and it will be necessary to inhale more frequently, whilst in warm conditions (above 30°C) nicotine will evaporate more readily and inhalation should be less frequent to avoid overdose. Maximum daily dose: 6 cartridges

Nicorette ® 15mg Inhalator: Max duration of treatment via protocol	To be supplied in packs of 4, maximum 6 cartridges per 24 hour period. Individual to be reviewed by a clinician at the next available opportunity. Individuals who have decided NOT to start a quit attempt and have been treated with NRT for nicotine withdrawal only will NOT receive a supply on discharge.
Details of the medicine: Nicorette QuickMist® 1mg	
Name, form and strength	Nicorette QuickMist® 1mg/spray mouthspray, as a duo pack with 150 sprays per pack. 0.07 ml contains 1 mg nicotine, corresponding to 1 mg nicotine/spray dose. Oromucosal spray.
Nicorette QuickMist® 1mg: Inclusion criteria	• Informed consent obtained. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion • Individual requires NRT, for use when individual normally would have smoked or vaped or if cravings emerge. • Individual 12 years or over • In case of any doubt, contact medical team
Nicorette QuickMist® 1mg: Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the individual is excluded" and "action to be taken if the individual declines treatment". • Hypersensitivity or allergy to any of the ingredients or excipients of the preparation (see SPC www.medicines.org.uk) • Individuals under 12 years • Non-smokers/ non-vapers • Individual who has been assessed by a clinician and deemed NRT inappropriate

Nicorette QuickMist® 1mg: Cautions/reasons for seeking further advice from a prescriber	• May contain ethanol • Also see General cautions • Due to the presence of a small amount of butylated hydroxytoluene (BHT), this medicine may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes
Nicorette QuickMist® 1mg: Route/method of administration	If using the oral spray for the first time, or if unit has not been used for 2 or more days, prime the unit before administration. Priming 1. Point the spray safely away from you and any other adults, children or pets that are near you. 2. Press the top of the QuickMist with your index finger 3 times until a fine spray appears. The oral spray should be released into the mouth, holding the spray as close to the mouth as possible and avoiding the lips. The individual should not inhale while spraying and avoid swallowing for a few seconds after use. The individual should not eat or drink when administering the oromucosal spray. Care should be taken not to spray the eyes whilst administering the mouth spray.
Nicorette QuickMist® 1mg: Dose and frequency	Use 1 or 2 sprays as required, when individual normally would have smoked or vaped or if cravings emerge. If after the first spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. Maximum single dose: 2 sprays per episode (up to 4 sprays every hour). Maximum daily dose: 64 sprays (4 sprays per hour over 16 hours) in any 24-hour period.
Nicorette QuickMist® 1mg: Max duration of	To be supplied in a duo pack, maximum 64 sprays per 24 hours.

treatment via protocol	Individual to be reviewed by a clinician at the next available opportunity. Individuals who have decided NOT to start a quit attempt and have been treated with NRT for nicotine withdrawal only will NOT receive a supply on discharge.

Details of the medicine: Nicorette® fruit 2mg lozenge	
Name, form and strength	Nicorette® fruit 2mg lozenge Each lozenge contains 2 mg nicotine (as nicotine resinate).
Nicorette® fruit 2mg lozenge: Inclusion criteria	• Informed consent obtained. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion • Individual requires NRT. • Individuals 12 years and over • In case of any doubt, contact medical team • This product is suitable for smokers who smoke 20 or less cigarettes per day.
Nicorette® fruit 2mg lozenge: Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the individual is excluded" and "action to be taken if the individual declines treatment". • Hypersensitivity or allergy to any of the ingredients or excipients of the preparation (see SPC www.medicines.org.uk) • Individuals under 12 years • Non-smokers • Individual who has been assessed by a clinician and deemed NRT inappropriate
Nicorette® fruit 2mg lozenge: Cautions/reasons for seeking further advice from a prescriber	• Lozenges can represent a choking hazard, therefore keep out of the reach of children. • Use with caution in individuals with aspiration and swallowing problems. • Contain a small amount of sulphites, which may rarely cause severe hypersensitivity reactions and bronchospasm • Also see General cautions

Nicorette® fruit 2mg lozenge: Route/method of administration	One lozenge should be placed in the mouth and allowed to dissolve; periodically move the lozenge from one side of the mouth to the other. A 2mg Lozenge dissolves completely, typically in 10-20 minutes. Do not chew or swallow the lozenge. Use within 3 months after removing the overwrap on the cardboard box. Store the lozenges in the original container in order to protect from moisture.
Nicorette® fruit 2mg lozenge: Dose and frequency	One lozenge every 1–2 hours as required, whenever the urge to smoke occurs or to prevent cravings in situations where these are likely to occur. Maximum daily dose: 15 lozenges
Nicorette® fruit 2mg lozenge: Max duration of treatment via protocol	To be supplied in packs of 20, maximum 15 lozenges to be taken per 24 hour period. Individual to be reviewed by a clinician at the next available opportunity. Individuals who have decided NOT to start a quit attempt and have been treated with NRT for nicotine withdrawal only will NOT receive a supply on discharge.
Details of the medicine: Nicorette Cools® lozenge 4mg	
Name, form and strength	Nicorette Cools® lozenge 4mg Each lozenge contains 4 mg nicotine (as nicotine resinate).

Nicorette Cools® lozenge 4mg: Inclusion criteria	• Informed consent obtained. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion • Individual requires NRT. • Individuals who smoke more than 20 cigarettes each day • Individual 12 years and over • In case of any doubt, contact medical team
Nicorette Cools® lozenge 4mg: Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Conditions outside of the clinical situations criteria • Consent not given. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "action to be taken if the individual is excluded" and "action to be taken if the individual declines treatment". • Hypersensitivity or allergy to any of the ingredients or excipients of the preparation (see SPC www.medicines.org.uk) • Individuals under 12 years • Non-smokers • Individual who has been assessed by a clinician and deemed NRT inappropriate
Nicorette Cools® lozenge 4mg: Cautions/reasons for seeking further advice from a prescriber	• Lozenges can represent a choking hazard, therefore keep out of the reach of children. • Use with caution in individuals with aspiration and swallowing problems. • Also see General cautions

Nicorette Cools® lozenge 4mg: Route/method of administration	One lozenge should be placed in the mouth and allowed to dissolve; periodically move the lozenge from one side of the mouth to the other. A Nicorette Cools 4mg Lozenge dissolves completely, typically in 10-20 minutes. Do not chew or swallow the lozenge. Use within 3 months after removing the overwrap on the cardboard box. Store the lozenges in the original container in order to protect from moisture.
Nicorette Cools® lozenge 4mg: Dose and frequency	One lozenge every 1-2 hours as required, whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. Maximum daily dose: 15 lozenges
Nicorette Cools® lozenge 4mg: Max duration of treatment via protocol	To be supplied in packs of 20, maximum 15 lozenges to be taken per 24 hour period. Individual to be reviewed by a clinician at the next available opportunity. Individuals who have decided NOT to start a quit attempt and have been treated with NRT for nicotine withdrawal only will NOT receive a supply on discharge.
Identification, management and reporting of adverse reactions (this section applies to all products contained in this protocol)	
Identification, management and reporting of adverse reactions	In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone to summon assistance if required. In case of anaphylaxis:- • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis policy

	• Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in individual's notes • Ensure all individual's records are marked **ALLERGIC TO NRT (list specific product)** • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers Report via Once for Wales Reporting System. The individual may confuse side-effects of the nicotine-replacement preparation with nicotine withdrawal symptoms, which may include: malaise, headache, dizziness, sleep disturbance, coughing, influenza–like symptoms, depression, irritability, increased appetite, weight gain, restlessness, anxiety, drowsiness, aphthous ulcers, decreased heart rate, and impaired concentration. Refer to BNF or SPC via medicines.org.uk or MHRA Products | Home for complete list for each specific product. Application site reactions are the most frequent adverse reaction associated with NiQuitin. Hypersensitivity reactions, including contact dermatitis and allergic dermatitis have also been reported. In the case of severe or persistent local reactions at the application site (e.g. severe erythema, pruritus or oedema) or a generalised skin reaction (e.g. urticaria, hives or generalised skin rashes) users should be instructed to discontinue use of NiQuitin and contact their physician. If there is a clinically significant increase in cardiovascular or other effects attributable to nicotine, the NiQuitin dose should be reduced or discontinued. If an individual using the 21mg patch experiences excessive side-effects, that do not resolve within a few days,

	contact a prescriber to consider changing to a medium or low-strength patch. Report any suspected adverse reactions to a doctor or prescriber and record in the individual's medical record. The individual's GP must also be informed. Healthcare practitioners and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.
Written/verbal advice for individual/ carer (this section applies to all products contained in this protocol)	
Written/verbal advice for individual/ carer	• Inform individual of medicine being supplied and rationale. • Reinforce the 'no smoking on site' message. • Inform individual that they are being treated within a protocol. • Provide patient information leaflet. Draw individual's or representative's attention to the label and patient information leaflet. Inform individual of possible side effects and their management. • Where appropriate advise individual/ carer how to administer the medication. • Where appropriate counsel on dosage regime. • Inform individual how/when to seek further medical advice. • Advise individual/carer to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact

	GP via surgery or emergency on call service, or ward staff (if applicable). • Users should be encouraged to stop smoking/vaping completely as soon as possible. • Refer patients for behavioural support via a smoking cessation practitioner, if available, or to Help Me Quit for follow up upon discharge. • Provide individual with additional patient information on nicotine replacement therapy and stopping smoking, using the approved ASH Wales leaflet (available in English and Welsh) at NRT Guide - Action on Smoking and Health (ash.wales) If relevant: • Pregnancy: Ideally smoking cessation should be achieved without NRT, however, the use of nicotine replacement therapy is preferable to the continuation of smoking during pregnancy. Nicotine replacement therapy should be considered alongside behavioural support, at the earliest opportunity in pregnancy and continued after pregnancy if needed. If patches are used, they should be removed before bed. The aim should be to use NRT for only 2-3 months – refer to smoking cessation and/or prescriber. • Breastfeeding: Ideally smoking cessation during lactation should be achieved without NRT. However, for women unable to quit on their own, NRT may be recommended by a healthcare professional to assist a quit attempt. Nicotine from smoking and NRT is present in breast milk; however, the amount of nicotine to which the infant is exposed from NRT is small and less hazardous than second-hand smoke. Using intermittent dose NRT preparations, compared with patches, may minimize the amount of nicotine in the breast milk as the time between administrations of NRT and feeding can be made as long as possible. Women should try to breastfeed just before they take the product. There is no or limited data

	regarding the effect of vaping in pregnancy or in lactating women. • For oral nicotine replacement therapy: Acidic beverages, such as coffee or fruit juice, may decrease the absorption of nicotine through the buccal mucosa and should be avoided for 15 minutes before the use of oral nicotine replacement therapy. • Patches: The user can bathe, swim or shower for short periods while wearing the nicotine transdermal patch. • Danger in small children: Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children: ○ Patch: After removal, the patch should be folded in half, adhesive side innermost, and placed inside the opened sachet, or in a piece of aluminum foil. The used patch should then be disposed of with care. ○ Lozenges can represent a choking hazard, therefore keep out of the reach of children

Records to be kept (this section applies to all products contained in this protocol)	
Records to be kept	Record consultation details as required by local procedures, in the individual's care record. For inpatients, the supplying healthcare professional must transcribe the supply onto the relevant section of the PTHB medicines administration record (See appendix B or appendix C for guidance on how to record on administration chart), indicating the name of the Healthcare professional who has made a supply via this protocol. If NRT has been initiated then the inpatient medication administration record should be endorsed in the special instructions box with 'Withdrawal Management'. In addition, record: • Name, address and date of birth of individual • Name and address of GP • Medical and drug history taken, including any allergies, nature of reaction and previous adverse events. • Criteria under which the individual fits the protocol. • Any reasons for exclusion or referral, including actions taken. • Any advice received from medical cover and advice given to individual/carer. • That valid informed patient consent to treatment was obtained, or a decision to treat made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate.

Records to be kept	• If the individual has refused treatment, and any advice given in this circumstance. • That the medication is being supplied in accordance with a Protocol- record title and version. • Date and time of supply. • Name, form, strength, route and dose • Quantity of drug supplied. • Expiry date • Relevant information given to the individual/carer The record must include the printed name and signature (which may be electronic) of the healthcare practitioner responsible for supply. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this Protocol should be kept for audit purposes in accordance with local policy. The head of department should arrange an annual retrospective audit of a minimum of 5 records over a 12-month period. This audit should sample 10% of individuals who have been treated according to this protocol in each location where the protocol has been used, to monitor compliance. The records must be reviewed for rationale behind administering or supplying the product, to check that supply was in accordance with the relevant monograph, that clear documentation is in place and that the competency checklist has been completed when authorising individuals to work to this protocol. The results should be available for review by the medicines management team upon request.

Key references

1. Summary of Product Characteristics www.medicines.org.uk:

   Nicorette® 15mg Inhalator accessed 25/05/24

   Nicorette QuickMist® 1mg accessed 25/05/24

   Nicorette® fruit 2mg lozenge accessed 25/05/24

   Nicorette Cools® lozenge 4mg accessed 25/05/24

2. Summary of Product Characteristics MHRA Products | Home

   NiQuitin Clear Patch ® 21mg/24hours accessed 23/05/24

3. BNF https://bnf.nice.org.uk accessed 23/05/24

4. BNFC https://bnfc.nice.org.uk accessed 23/05/24

5. AWMSG Initial Clinical Management of Adult Smokers in Secondary Care June 2021

Appendix A: Staff Permitted to use the Protocol Signature sheet

Authorising Manager: I confirm that the practitioners named below are suitably trained and competent to work under this Protocol. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the Protocol to work under it.
The authorising professional MUST use the competency checklist (below) to evidence the competency.
Practitioner: By signing this Protocol you are indicating that you agree to its contents and that you will work within it. Protocols do not remove inherent professional obligations or accountability. It is the responsibility of each authorised professional to practise only within the bounds of their own competence and professional code of conduct.
I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it within my professional code of conduct.

Printed name of healthcare professional	Signature of healthcare professional	Printed name of senior representative authorising health professional (Authorising Manager)	Signature of senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list, which should be kept by PTHB for 25 years after the protocol expires. This list must be made available to the medicines management department for audit purposes. The healthcare professional should retain a copy of the document after signing.

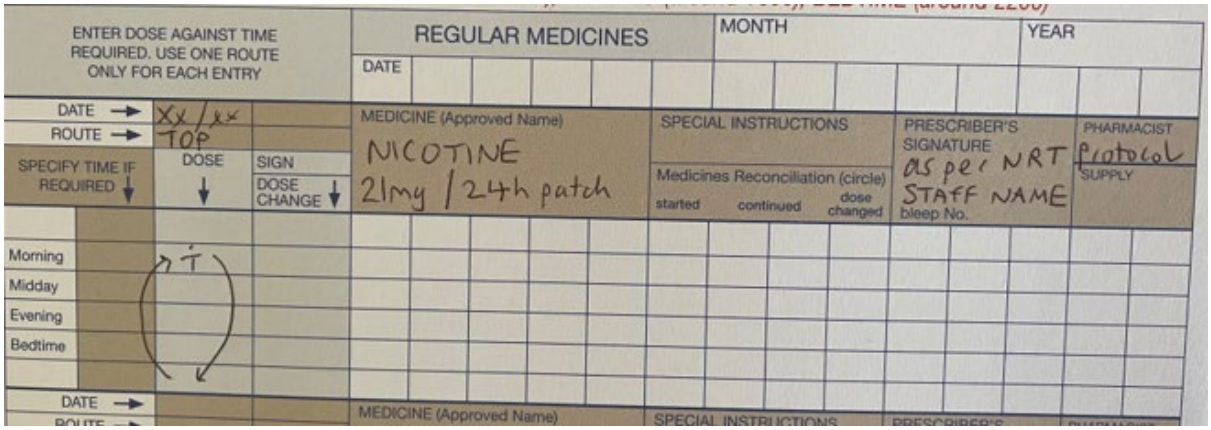
Competency check list for manager/senior team lead to use as part of the authorising process**.** Review of authorisation will take place on each Protocol update and at the individual's annual PADR.

Name: **Role:** Current contract with PTHB (please circle): YES / NO		Sign / Initial	Further training identified (Y/N) Specify in comments	Comments	Actioned and complete
1	The Protocol sign off is for the following Protocol: MMP 453: Supply of NRT to individuals to relieve and/or prevent craving and nicotine withdrawal symptoms whilst unable to smoke or vape on hospital grounds				
2	We have discussed the expiry date of the Protocol and are using a version accessed electronically				
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD				
4	The protocol has been read in full by the staff member				
5	The identified training has been completed as specified in the Protocol and is in date				
6	We have discussed some examples of inclusion criteria and exclusion criteria				
7	The staff member is confident in the administration method and doses				

Staff member print & sign name		Date
Manager/senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member. A copy of this form should be kept by service lead in the training file- this will be subject to audit.

Appendix B: Guidance on recording on regular side of chart



ENTER DOSE AGAINST TIME REQUIRED. USE ONE ROUTE ONLY FOR EACH ENTRY

REGULAR MEDICINES | MONTH | YEAR

DATE

DATE → Xx / xx
ROUTE → TOP

SPECIFY TIME IF REQUIRED ↓ | DOSE ↓ | SIGN | DOSE CHANGE ↓

MEDICINE (Approved Name): NICOTINE 21mg / 24h patch

SPECIAL INSTRUCTIONS

Medicines Reconciliation (circle): started | continued | dose changed

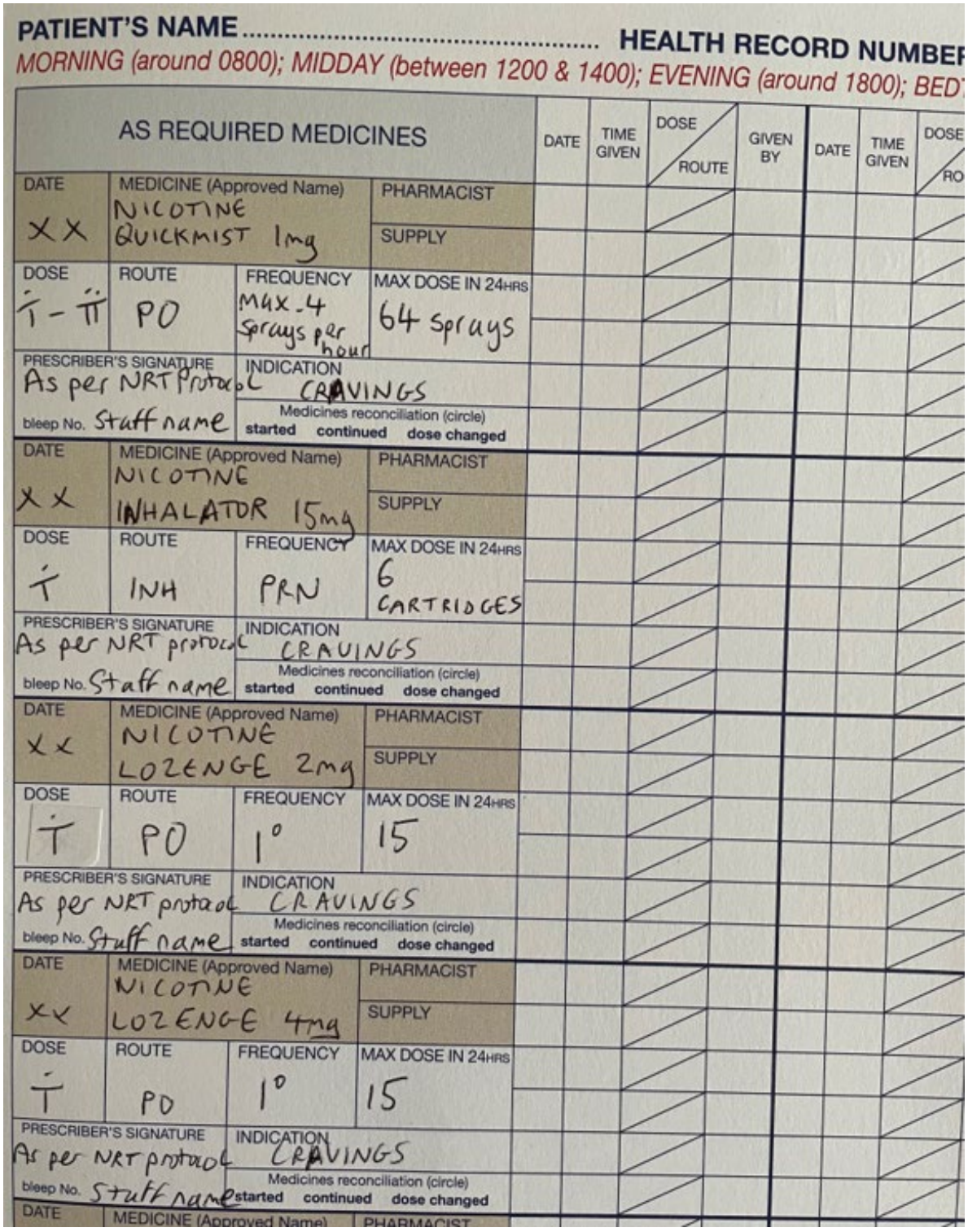
PRESCRIBER'S SIGNATURE: as per NRT STAFF NAME
bleep No.

PHARMACIST: protocol
SUPPLY

Morning
Midday
Evening
Bedtime

DATE →
MEDICINE (Approved Name)
SPECIAL INSTRUCTIONS

Appendix C: Guidance on recording on PRN section of chart



PATIENT'S NAME ..... HEALTH RECORD NUMBER

MORNING (around 0800); MIDDAY (between 1200 & 1400); EVENING (around 1800); BED

AS REQUIRED MEDICINES

DATE: XX
MEDICINE (Approved Name): NICOTINE QUICKMIST 1mg
PHARMACIST:
SUPPLY:
DOSE: 1 - 2
ROUTE: PO
FREQUENCY: MAX 4 sprays per hour
MAX DOSE IN 24HRS: 64 sprays
PRESCRIBER'S SIGNATURE: As per NRT Protocol
INDICATION: CRAVINGS
bleep No. Staff name
Medicines reconciliation (circle) started continued dose changed

DATE: XX
MEDICINE (Approved Name): NICOTINE INHALATOR 15mg
PHARMACIST:
SUPPLY:
DOSE: 1
ROUTE: INH
FREQUENCY: PRN
MAX DOSE IN 24HRS: 6 CARTRIDGES
PRESCRIBER'S SIGNATURE: As per NRT protocol
INDICATION: CRAVINGS
bleep No. Staff name
Medicines reconciliation (circle) started continued dose changed

DATE: XX
MEDICINE (Approved Name): NICOTINE LOZENGE 2mg
PHARMACIST:
SUPPLY:
DOSE: 1
ROUTE: PO
FREQUENCY: 1°
MAX DOSE IN 24HRS: 15
PRESCRIBER'S SIGNATURE: As per NRT protocol
INDICATION: CRAVINGS
bleep No. Staff name
Medicines reconciliation (circle) started continued dose changed

DATE: XX
MEDICINE (Approved Name): NICOTINE LOZENGE 4mg
PHARMACIST:
SUPPLY:
DOSE: 1
ROUTE: PO
FREQUENCY: 1°
MAX DOSE IN 24HRS: 15
PRESCRIBER'S SIGNATURE: As per NRT protocol
INDICATION: CRAVINGS
bleep No. Staff name
Medicines reconciliation (circle) started continued dose changed

DATE
MEDICINE (Approved Name)
PHARMACIST

DATE | TIME GIVEN | DOSE / ROUTE | GIVEN BY | DATE | TIME GIVEN | DOSE / RO