Patient Group Direction For The Supply Of Naloxone (Prenoxad® Or Nasal Spray) By Approved Healthcare Professionals Working Within NHS Grampian

Lead Author: Pharmacist Substance And Medicines Use	**Consultation Group**: See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NHSG Identifier: MGPG/PGD/NaloxTH/ 1639	**Review Date:** April 2027 **Expiry Date:** April 2028	**Date Approved:** April 2025

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 6

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	Supersedes NHSG/PGD/NaloxTH/MGPG1226, Version 5	
Date of change	**Summary of Changes**	**Section heading**
July 2024	Changed to current template.	
July 2024	Added midwives.	Professional qualifications
July 2024	Added naloxone 1.26mg nasal spray.	Throughout
January 2025	Inclusion criteria amended to include those who are likely to witness an overdose whether or not consent from the person at risk can be obtained.	Inclusion criteria

NHGS Identifier: MGPG/PGD/NaloxTH/1639
Keyword(s): Patient group direction naloxone prenoxad® nyxoid opioid overdose nasal spray

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	July 2024
	Completed:	February 2025
	Approved:	April 2025 (published April 2025)
	Amended and re-authorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Mairi Hope **Title:** GP With Specialist Interest In Addictions **Contact email:** mairi.hope@nhs.scot **Signature:** ..... Mairi Hope ..... **Date:** 17/04/2025
Senior representative of the professional group who will provide care under the direction	**Name:** Jenny Gibb **Title:** Nurse Director **Contact email:** jennifer.gibb2@nhs.scot **Signature:** ..... J Gibb ..... **Date:** 08/04/2025
Lead author	**Name:** Jill Carnegie **Title :** Pharmacist Substance And Medicines Use **Contact email:** jill.carnegie@nhs.scot **Signature:** ..... **Date:** 07/04/2025
Pharmacist	**Name:** Kirsty Regan **Title :** Clinical Pharmacist **Contact email:** kirsty.regan@nhs.scot **Signature:** ..... K Regan ..... **Date:** 08/04/2025

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		18/04/2025

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and is best practice to have a representative of the professional group who will provide care under the direction.

Name:	Title:
Jill Carnegie	**Lead Author: Pharmacist Substance And Medicines Use**
Kirsty Regan	**Pharmacist: Clinical Pharmacist**
Mairi Hope	**Medical Practitioner: GP With Specialist Interest In Addictions**
Jenny Gibb	**Senior Representative: Nurse Director**
Christina Anderson	Clinical nurse specialist on behalf of the acute pain team
Liz Cheung	Lead midwife for maternity and women's services
Alison McGruther	Chief nurse

Patient Group Direction For The Supply Of Naloxone (Prenoxad® Or Nasal Spray) By Approved Healthcare Professionals Working Within NHS Grampian

Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD, to supply naloxone as included in the naloxone formulary (Appendix 4) to individuals aged 14 years and over at risk of, or likely to witness, opioid overdose. This PGD applies to services which are not classified as Drug Treatment Services. Drug Treatment Services (including community pharmacies who deliver substance misuse and injecting equipment services as per local Service Level Agreements) should refer to the relevant documentation for their service. This reflects the change in legislation introduced by the Department of Health in 2015 which aims to widen the availability of naloxone. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals who, • Are at risk of opioid overdose, and who have demonstrated an awareness and understanding of naloxone administration and supply. Individuals at risk of opioid overdose may include individuals prescribed opioids. • Are likely to witness an overdose (such as a friend or family member of someone at risk of opioid overdose) and who have demonstrated an awareness and understanding of naloxone administration and supply. **Note:** The Grampian Take Home Naloxone Key Points Sheet (Appendix 3) is designed to support delivery of this intervention. Prior to the supply of the medicine, valid consent to receiving supply under this PGD must be obtained. Consent must be in line with current NHSG consent policy.

Exclusion criteria	Naloxone will not be supplied to individuals: • Who have not been able to demonstrate sufficient understanding of what naloxone does and/or how to administer it. • Individuals for whom no valid consent has been received.
Supply to children and young people	Overdose awareness training and supply of naloxone to children and young people is not a decision that should be made in isolation. It will form part of the wider considerations of child welfare and protection that fit with existing child protection guidelines (National Guidance for Child Protection in Scotland 2021) to ensure that children and young people are safe and protected from harm. Practitioners should ensure that a referral is made to Children and Families Social Work if that has not already been done to allow assessment of the needs and risk for the child. Each case should be considered using GIRFEC principles using the National Practice Model and National Risk Assessment Framework in a multi-agency context to assess need and risk. It is essential that the multi-agency "Team around the Child" is involved in the planning and decision making when considering whether to include the child in this aspect of their parents/carers management of overdose. The Child's Plan should include this aspect of the plan. Where a child or young person is in a position where they could witness or experience opioid overdose and where the environment has been assessed as safe for the child to remain, training and/or supply of naloxone may be appropriate. The staff member should assess whether the child has sufficient ability and understanding to be trained to: • Contact emergency services by dialling 999 and asking for an ambulance • Administer naloxone (nasal product should be supplied for those aged 14 to 16 years) • Undertake basic life support • Watch for a response and decide on further action needed whilst waiting for emergency services. Training should be tailored according to capacity. For example it may be that a child can understand when and how to contact an ambulance but would not be able to administer basic life support or administer naloxone.

Precautions and special warnings	The person should understand the short acting nature of naloxone. An apparently successful outcome after administration of naloxone may be followed later by a return to respiratory depression and overdose symptoms. The person should be advised of the requirement to contact the emergency services wherever opioid overdose is suspected and to avoid/advise against further drug use which increases risk of return to overdose. Naloxone may cause hypersensitivity reactions in a small number of susceptible individuals. Medical advice must be sought as soon as possible from a medical practitioner if a recipient develops any signs of hypersensitivity.
Action if excluded from treatment	• Individuals who are not eligible to receive a supply of naloxone may still be provided with training in basic life support and naloxone administration. • Individuals under 14 years may still be trained in overdose awareness and naloxone administration where deemed competent but are ineligible for supply of naloxone under this PGD. Where the child is themselves at risk of opioid overdose medical advice should be sought and they should be signposted or referred to appropriate services as a matter of urgency. • Advice should be given on alternative treatment strategies including harm reduction and overdose prevention. • Individuals should be advised of the requirement to contact the emergency services wherever overdose is suspected. • Individuals should be referred to an appropriate healthcare professional and/or advised on available treatment services if appropriate. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	• Provide details on where they can access naloxone supply in the future. A list of current services can be accessed here. Patients can also download the Aberdeen Protects App for up to date information on the go. The Aberdeen protects app currently only lists suppliers within Aberdeen city. • Document that the supply was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	See individual monographs.
Legal status	Medicines referred to in this PGD are all Prescription-only Medicines (POM). In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Is the use out with the SmPC?	Use outwith the SmPC is not permitted under this PGD.
Dosage/Maximum total dose	See individual medicine monographs.
Frequency of dose/Duration of treatment	See individual medicine monographs.
Maximum or minimum treatment period	See individual medicine monographs.
Route/Method of administration	See individual medicine monographs.
Quantity to be supplied	See individual medicine monographs.
Storage requirements	See individual medicine monographs.
Follow-up (if applicable)	During future contacts, clinicians should check with clients that they still hold a supply of naloxone and understand how to use it. Ensure people are made aware of other access points for naloxone, e.g. community pharmacy, drug treatment services.
Advice (Verbal)	Prior to making a supply of naloxone staff should ensure that the individual at risk and nominated representative(s) are aware of the following information or advice. The Key Information Sheet (Appendix 3) will support this.

	• The individual should be informed of the importance of contacting ambulance services at the earliest opportunity where opioid overdose is suspected. Ambulance services should be contacted by dialling 999. • Encourage the person to carry the supply of naloxone with them at all times. • Ensure that the person has a basic understanding of overdose awareness, basic life support and can demonstrate how to administer naloxone. • Provide advice on other supportive strategies including harm reduction and overdose prevention. • Explain treatment and course of action. • On arrival of the ambulance they should advise ambulance staff of how the individual has responded and details of any adverse effects. • Highlight information included in the manufacturers Patient Information Leaflet. • Advise on available services for accessing further training and/or resupplies of used, lost or expired naloxone. • Individuals should be referred to an appropriate healthcare professional and/or advised on available treatment services if appropriate. • Any action or referral should be recorded in the individual's notes as appropriate. • Advise individual what to expect and of the possible side effects and their management. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unsuitable, sufficient information should be given in a language that they can understand. Written advice specific to each product is listed in the individual medication monographs.
Identifying and managing possible adverse reactions	Administration of naloxone in opioid overdose is a life-saving intervention which should not be delayed. However abrupt reversal of opioid effects by the administration of naloxone may cause the following reactions: • In people who are physically dependent on opioids, rapid reversal of opioid effects may precipitate an acute withdrawal syndrome, inducing nausea, vomiting, sweating, tachycardia, hyperventilation, hypertension and tremor.

	• Most common reactions include hypotension, hypertension, ventricular tachycardia. • Very rare or less common reactions include ventricular fibrillation (very rarely), cardiac arrest, hyperventilation, dyspnoea, pulmonary oedema, less commonly agitation, excitement and paraesthesia. • In people with pre-existing cardiac disease or in those taking potentially cardiotoxic drugs, serious adverse effects have been reported such as pulmonary oedema, myocardial ischaemia, hypotension, hypertension, ventricular tachycardia and fibrillation. • Symptoms of withdrawal in foetuses during pregnancy. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC:** BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC), registered Midwives as recognised by the Nursing and Midwifery Council (NMC), and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/parents/carers capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Having completed the SDF e-learning package or recognised Naloxone Take Home Programme Training • Having watched the videos on the administration of the two naloxone products available for supply www.nyxoid.com/uk and www.prenoxadinjection.com/video/admin.mp4 and Naloxone Nasal Spray Guidance for Healthcare Professionals • Competent to undertake supply of the medicine • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the

	medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Nurses and midwives working within NHS Grampian can be authorised to supply the medicines specified in this PGD by their Nurse/Midwife Manager or Substance Misuse Service Clinical Lead/Team Lead in NHS Grampian. Pharmacists working within NHS Grampian can be authorised to supply the medicines specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.
Record of supply	An electronic or paper record must be completed to allow audit of practice. An electronic record of the screening and subsequent supply, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic recording processes.

	If a paper record is used for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD. This should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route (batch number and expiry date for injectable medicines) of the medicine(s) supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine, and who undertook the assessment of the individual's clinical suitability for the administration/supply of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • Child Health Information Services if appropriate • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • Secondary Care Medical Notes • HEPMA • Occupational health systems • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.

References	**Electronic Medicines Compendium** Nyxoid 1.8mg nasal spray, solution in a single-dose container - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Date of revision of text 07/05/24, accessed 27/09/24. Prenoxad 1mg/mL Solution for Injection in a pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Date of revision of text 02/06/21, accessed 27/09/24. **MHRA Products** Microsoft Word - 2883045380427683876_spc-doc.doc Date of revision of text 21/12/22, accessed 27/09/24. British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 27/09/24.

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Grampian Take Home Naloxone Key Points Sheet **Appendix 3**

Be Prepared For An Opioid Emergency

WHO IS AT RISK OF OPIOID OVERDOSE?

- People who use prescription opioids, in particular those taking higher doses (equivalent to 50milligrams of morphine or more per day)
- People who use any type of opioid in combination with other sedating substances such as benzodiazepines or alcohol
- People who use any type of opioid and have medical conditions such as HIV, liver, lung disease or who suffer from depression
- People with opioid dependence, in particular following reduced tolerance (following detoxification, release from prison, breaks in or stopping treatment)
- People who inject opioids
- Anyone in contact with people who use opioids (including prescription opioids)

WHAT ARE THE SIGNS OF OPIOID OVERDOSE?

- **UNCONSCIOUS OR NOT RESPONDING:** Not waking up or responding to voice commends or touch. Shake shoulders. Speak clearly in both ears
- **APPEARANCE:** Blue/grey skin and lips. Clammy. Very small/pinpoint pupils
- **BREATH:** Very slow or irregular breathing or no breathing at all. May also be a rasping or snoring sound

KNOWS HOW TO RESPOND

- Call 999 and ask for an **AMBULANCE** - give location
- Let them know that the person is:
  - **"UNCONSCIOUS BUT BREATHING" -** Put them into recovery position
  - **"UNCONSCIOUS AND NOT BREATHING" -** Start CPR
- Stay with the person
- Bust myths - DO NOT walk person around, put in shower/bath, slapping etc

KNOWS HOW NALOXONE WORKS

- Reverses the effects of opioid drugs but starts to wear off after 20 to 30 minutes
- Only works on opioid drugs (safe to use even if unsure what has been taken)
- Give a dose every 2 to 3 minutes until either: -
  - Person comes round **OR** Emergency services arrive and take over **OR** there is no naloxone left

CHOOSE PRODUCT TO SUPPLY. USE PRODUCT LEAFLET TO GO OVER ITS USE

HOW TO USE PRENOXAD® INJECTION

- Keep sealed until ready to use
- Twist cap off syringe and twist on needle
- Inject into outer thigh or upper arm muscle
- Give one dose at a time. Repeat every 2 to 3 minutes if no response
- Place in yellow box between injections and after used (sharps bin)

HOW TO USE NALOXONE NASAL SPRAY

- DO NOT TEST THE SPRAY FIRST – THERE IS ONLY ONE SPRAY IN EACH NASAL SPRAY (Package contains 2 kits)
- Tilt head back
- Put the nasal spray into the nostril and press the plunger
- If no response after 2 to 3 minutes open another kit and give another dose of naloxone in the other nostril

IF YOU HAVE TO USE A KIT OR IT IS OUT OF DATE – REMEMBER TO GET ANOTHER ONE

Appendix 4 - NHS Grampian Naloxone Formulary

NHS Grampian Naloxone Formulary

The information in these monographs is not exhaustive. They must be read in conjunction with the current issue of the British National Formulary, and the Summary of Product Characteristics for each medicine.

Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®) (Supply)	
Indication	Emergency use in the home or non-medical setting for the reversal of respiratory depression induced by natural and synthetic opioids (known or suspected opioid overdose).
Inclusion Criteria	As per main PGD inclusion criteria and additionally: Individuals aged 16 years or over.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: Individuals aged under 16 years.
Precautions and Special Warnings	The person should understand the short acting nature of naloxone. An apparently successful outcome after administration of naloxone may be followed later by a return to respiratory depression and overdose. The person should be advised of the requirement to contact the emergency services wherever opioid overdose is suspected and to avoid/advise against further drug use which increases risk of return to overdose. Naloxone may cause hypersensitivity reactions in a small number of susceptible individuals. Medical advice must be sought as soon as possible from a doctor if a recipient develops any signs of hypersensitivity.
Legal Status	Naloxone hydrochloride (Prenoxad®) is a Prescription-only Medicine (POM). In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. Naloxone hydrochloride (Prenoxad®) is for use in adults and adolescents 16 years or over (see Patient Information Leaflet).
Dose/Maximum total dose	Individuals should be advised to administer Naloxone hydrochloride (Prenoxad®) as follows; • A single dose (400micrograms or 0.4mL) of naloxone should be administered by intramuscular injection into the thigh or upper arm. Each syringe contains five doses which are clearly marked.

Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®) (Supply)	

Frequency of dose/Duration of treatment	Individuals should be advised:
	
	• If there is no response after 2 to 3 minutes a further dose should be administered. This should be repeated until either:
	  ○ The person regains consciousness or
	  ○ All 5 doses have been used (further doses may be given if available) or
	  ○ The emergency services arrive and take over.
	
	Refer to current edition of the BNF and SmPC for further information. Information can also be found on the Prenoxad® website.
	
	Healthcare professionals should discuss where naloxone fits in the basic life support process.
	
	Unresponsive and breathing normally.
	
	The casualty should be placed in the recovery position and naloxone administered every 2 to 3 minutes as required.
	
	Unresponsive and not breathing normally.
	
	Cardiopulmonary resuscitation (CPR) should be started. Naloxone should be administered following the 1st cycle of CPR and every 3 cycles thereafter.

Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	The healthcare professional should advise that the dose should be administered intramuscularly into the outer thigh (preferred) or upper arm. It may be administered through clothing if necessary.
Quantity to be supplied	People at risk of future opioid overdose can receive: • One naloxone hydrochloride (Prenoxad®) kit for intramuscular use. • One additional naloxone hydrochloride (Prenoxad®) kit to hold as a spare supply if required and circumstances support this, e.g. splits time between family home and other property. • Two different formats of naloxone hydrochloride may be supplied in one transaction, e.g. one pack of Nyxoid® and one Prenoxad® kit.

Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®) (Supply)	
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Dizziness, headache, hypertension, hypotension, nausea, tachycardia, vomiting.
Advice	Individuals should also be issued with the naloxone hydrochloride (Prenoxad®) Injection Assembly and Administration Guide" tear off sheet (orderable from NHS Grampian Health Information Resources Service www.nhsghpcat.org). The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Copies of all PIL and can be found at www.medicines.org.uk or www.mhra.gov.uk/spc-pil/index.htm
Follow up (If applicable)	Individuals at risk of opioid overdose should be encouraged, and if possible supported, to access treatment. In the event of experiencing an opioid overdose they should be encouraged to discuss this with their healthcare treatment provider. This includes suspected adverse effects.
Storage	This medicinal product does not require any special temperature storage conditions. Keep the syringe in the plastic box in order to protect from light. Store in the original container. Advise on safe storage, handling and disposal of the product. The syringe should be placed in the hard yellow case and returned to a community pharmacy or handed to the paramedic for disposal.

Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply)	
Indication	Emergency use in the home or non-medical setting for the reversal of respiratory depression induced by natural and synthetic opioids (known or suspected opioid overdose).
Inclusion Criteria	As per main PGD inclusion criteria and additionally: Individuals aged 14 years and over.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: Individuals aged under 14 years.
Precautions and Special Warnings	The person should understand the short acting nature of naloxone. An apparently successful outcome after administration of naloxone may be followed later by a return to respiratory depression and overdose. The person should be advised of the requirement to contact the emergency services wherever opioid overdose is suspected and to avoid/advise against further drug use which increases risk of return to overdose. Naloxone may cause hypersensitivity reactions in a small number of susceptible individuals. Medical advice must be sought as soon as possible from a doctor if a recipient develops any signs of hypersensitivity.
Legal Status	Naloxone hydrochloride (Nyxoid®) is a Prescription-only Medicine (POM). In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.
Dose/Maximum total dose	Naloxone hydrochloride (Nyxoid®) is available as a pack of two individually sealed single dose nasal sprays and a patient information leaflet. Individuals should be advised that: • The nasal spray should not be primed or tested prior to use as it only contains a single dose of naloxone. • The contents of a nasal spray (1.8mg) should be sprayed into the casualty's nostril.

Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply)	
Frequency of dose/Duration of treatment	Individuals should be advised that: • If there is no response after 2 to 3 minutes a second nasal spray should be sprayed into the other nostril. • If the person does not respond to two doses, further doses may be given (if available). Healthcare professionals should discuss where naloxone fits in the basic life support process. **Unresponsive and breathing normally**. The casualty should be placed in the recovery position and naloxone administered every 2 to 3 minutes as required. **Unresponsive and not breathing normally**. Cardiopulmonary resuscitation (CPR) should be started. Naloxone should be administered following the 1st cycle of CPR and every 3 cycles thereafter. Refer to current edition of the BNF and SmPC for further information. More information, including a video, can be found on the Nyxoid® website https://nyxoid.com/uk
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	The dose should be administered into one nostril with repeated doses being sprayed into alternate nostrils
Quantity to be supplied	People at risk of future opioid overdose can receive: • One pack of naloxone hydrochloride nasal spray • An additional pack of naloxone hydrochloride nasal spray to hold as a spare supply if required, e.g. splits time between family home and other property • Two different formats of naloxone hydrochloride may be supplied in one transaction, e.g. one pack of naloxone nasal spray and one Prenoxad® kit.

Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply)	
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Dizziness, headache, hypertension, hypotension, nausea (very common), tachycardia, vomiting.
Advice	Individuals should also be issued with a Nyxoid® patient information leaflet. The Nyxoid® leaflet can also be printed from the following link: www.medicines.org.uk/emc/rmm/1278/Document The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Copies of all PIL and can be found at www.medicines.org.uk or www.mhra.gov.uk/spc-pil/index.htm
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.
Storage	Do not freeze.

Naloxone Hydrochloride Dihydrate 1.26mg Per Nasal Spray (Supply)	
Indication	Emergency use in the home or non-medical setting for the reversal of respiratory depression induced by natural and synthetic opioids (known or suspected opioid overdose).
Inclusion Criteria	As per main PGD inclusion criteria and additionally: Individuals aged 16 years or over.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: Individuals aged under 16 years.
Precautions and Special Warnings	The person should understand the short acting nature of naloxone. An apparently successful outcome after administration of naloxone may be followed later by a return to respiratory depression and overdose. The person should be advised of the requirement to contact the emergency services wherever opioid overdose is suspected and to avoid/advise against further drug use which increases risk of return to overdose. Naloxone may cause hypersensitivity reactions in a small number of susceptible individuals. Medical advice must be sought as soon as possible from a doctor if a recipient develops any signs of hypersensitivity.
Legal Status	Naloxone hydrochloride is a Prescription-only Medicine (POM). In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. Naloxone 1.26mg nasal spray is for use in adults and adolescents 16 years or over (see patient information leaflet).
Dose/Maximum total dose	Naloxone hydrochloride is available as a pack of two single dose nasal sprays and a patient information leaflet. The doses are contained within a plastic case known as a “pebble”. Individuals should be advised that: • The nasal spray should not be primed or tested prior to use as it only contains a single dose of naloxone. • The contents of a nasal spray (1.26mg) should be sprayed into the casualty’s nostril.

Naloxone Hydrochloride Dihydrate 1.26mg Per Nasal Spray (Supply)	
Frequency of dose/Duration of treatment	Individuals should be advised that: • If there is no response after 2 to 3 minutes a second nasal spray should be sprayed into the other nostril. • If the person does not respond to two doses, further doses may be given (if available). Healthcare professionals should discuss where naloxone fits in the basic life support process. **Unresponsive and breathing normally**. The casualty should be placed in the recovery position and naloxone administered every 2 to 3 minutes as required. **Unresponsive and not breathing normally**. Cardiopulmonary resuscitation (CPR) should be started. Naloxone should be administered following the 1st cycle of CPR and every 3 cycles thereafter. Refer to current edition of the BNF and SmPC for further information. More information, including a video, can be found at this website. https://naloxone.uk/prescribed-naloxone-1-26mg-nasal-spray-likely-to-witness-an-opioid-overdose/. There is a section for healthcare professionals and for patients.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of Administration	The dose should be administered into one nostril with repeated doses being sprayed into alternate nostrils.
Quantity to be supplied	People at risk of future opioid overdose can receive: • One pack of naloxone hydrochloride nasal spray • An additional pack of naloxone hydrochloride nasal spray to hold as a spare supply if required, e.g. splits time between family home and other property • Two different formats of naloxone hydrochloride may be supplied in one transaction, e.g. one pack of nasal spray and one Prenoxad® kit.

Naloxone Hydrochloride Dihydrate 1.26mg Per Nasal Spray (Supply)	
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Dizziness, headache, hypertension, hypotension, nausea (very common), tachycardia, vomiting.
Advice	Are there additional patient leaflets? The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Copies of all PIL and can be found at www.mhra.gov.uk/spc-pil/index.htm
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.
Storage	Do not freeze. Keep single dose containers in the plastic cover to protect from light.