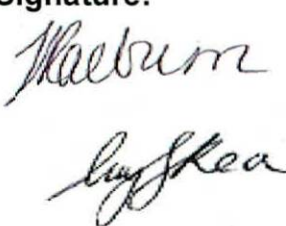



**Patient Group Direction For The Supply Of Naloxone (Prenoxad® Or Nyxoid®) By Approved Healthcare Professionals Working Within NHS Grampian**

<b>Lead Author:</b> Specialist Pharmacists in Substance Misuse	<b>Consultation Group:</b> See relevant page in the PGD	<b>Approver:</b> Medicines Guidelines and Policies Group  <b>Authorisation:</b> NHS Grampian
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<b>Signature:</b> 		<b>Signature:</b> 
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<b>NHSG Identifier:</b> NHSG/PGD/NaloxTH/ MGPG1226	<b>Review Date:</b> February 2024  <b>Expiry Date:</b> February 2025	<b>Date Approved:</b> February 2022
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**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 5**

**Revision History:**

<b>Reference and approval date of PGD that has been adapted and/or superseded</b>		Supersedes previous document NHSG/PGD/NaloxTH/MGPG973, Version 4
<b>Date of change</b>	<b>Summary of Changes</b>	<b>Section heading</b>
August 2021	Changed to current template.	
August 2021	Information added to include the intranasal product (Nyxoid®).	Throughout document
August 2021	Inclusion criteria amended to 14 years and over.	Throughout document
August 2021	Added information on supply to children and young people.	Supply to children and young people
August 2021	NHS Grampian approved training has been amended to include SDF training and videos.	Specialist competencies
December 2021	Reformatted medication monographs in body of text into a formulary in Appendices.	Appendix 4 – NHSG Naloxone Formulary
February 2022	Title changed to reflect naloxone monographs.	Throughout

**NHGS Identifier:**

NHSG/PGD/NaloxTH/MGPG1226

**Keyword(s):**PGD Patient Group Direction naloxone supply  
take home opioid overdose

**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:	August 2021
	Completed:	December 2021
	Approved:	February 2022 (published – March 2022)
	Amended:	


## Organisational Authorisations

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

PGD Developed/Reviewed by;

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<b>Senior representative of the professional group who will provide care under the direction</b>	<p><b>Name:</b> Carol MacDougall</p> <p><b>Title:</b> Lead Nurse Drug and Alcohol Care Team</p> <p><b>Contact email:</b> <a href="mailto:carol.mcdougall2@nhs.scot">carol.mcdougall2@nhs.scot</a></p> <p><b>Date signed:</b> 02/03/2022</p> <p><b>Signature:</b> .....  .....</p>
<b>Lead author</b>	<p><b>Name:</b> Fiona Raeburn</p> <p><b>Title :</b> Specialist Pharmacist in Substance Misuse</p> <p><b>Contact email:</b> <a href="mailto:fiona.raeburn@nhs.scot">fiona.raeburn@nhs.scot</a></p> <p><b>Date signed:</b> 22/02/2022</p> <p><b>Signature:</b> .....  .....</p>
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**Approved and authorised for use within NHSG by;**

<b>Medicines Guidelines and Policies Group Chair</b>	<b>Signature</b>	<b>Date Signed</b>
Lesley Coyle		17/02/2022

**Management and Monitoring of Patient Group Direction**

**PGD Consultative Group**

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

**Name:**

**Title:**

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Johanna Hanschell

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Carol MacDougall

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**Pharmacist:** Clinical Pharmacist Unscheduled Care

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Mental Health Specialist Nurse, Moray Integrated Drug and  
Alcohol Service

Specialist Pharmacist, Substance Misuse Service

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

## **Clinical indication to which this PGD applies**

<p><b>Definition of situation/Condition</b></p>	<p>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 (<a href="#">Appendix 4</a>) to individuals aged 14 years and over at risk of, or likely to witness, opioid overdose.</p> <p>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 document "<a href="#">Guidance For Drug Treatment Services In Grampian Undertaking Supply Of Naloxone To People At Risk Of Opioid Overdose, Significant Others And Services In Contact With Those At Risk</a>". This reflects the <a href="#">change in legislation</a> introduced by the Department of Health in 2015 which aims to widen the availability of naloxone.</p> <p>This PGD should be used in conjunction with the recommendations in the current <a href="#">British National Formulary (BNF)</a>, <a href="#">British National Formulary for Children (BNFC)</a> and the individual Summary of Product Characteristics (SmPC).</p>
<p><b>Inclusion criteria</b></p>	<p>Individuals who,</p> <ul style="list-style-type: none"> <li>• Are at risk of opioid overdose, and who have demonstrated an awareness and understanding of naloxone administration and supply.</li> <li>• Are a nominated representative of a named individual who have demonstrated an awareness and understanding of the naloxone supply may receive a supply to hold on the individual's behalf. The named individual's consent for representatives to act on their behalf should be recorded in the appropriate patient record.</li> </ul> <p><b>Note:</b> The Grampian Take Home Naloxone Key Points Sheet (<a href="#">Appendix 3</a>) and <a href="#">opioid equivalence table</a> are designed to support delivery of this intervention.</p> <p>Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHSG consent policy.</p>

<b>Exclusion criteria</b>	<p>Naloxone will not be supplied to individuals:</p> <ul style="list-style-type: none"> <li>• Who have not been able to demonstrate sufficient understanding of what naloxone does and/or how to administer it.</li> <li>• Where there is no valid consent.</li> </ul>
<b>Supply to children and young people</b>	<p>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 (<a href="#">National Guidance for Child Protection in Scotland 2014</a>) 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 <a href="#">GIRFEC principles</a> using the <a href="#">National Practice Model</a> and <a href="#">National Risk Assessment Framework</a> in a multi-agency context to assess need and risk.</p> <p>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:</p> <ul style="list-style-type: none"> <li>• Contact emergency services by dialling 999 and asking for an ambulance</li> <li>• Administer naloxone (nasal product should be supplied for those aged 14-16 years)</li> <li>• Undertake basic life support</li> <li>• Watch for a response and decide on further action needed whilst waiting for emergency services.</li> </ul> <p>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.</p>



<b>Precautions and special warnings</b>	<p>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.</p> <p>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.</p>
<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>• Individuals who are not eligible to receive a supply of naloxone may still be provided with training in basic life support and naloxone administration.</li> <li>• 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.</li> <li>• Advice should be given on alternative treatment strategies including harm reduction and overdose prevention.</li> <li>• Individuals should be advised of the requirement to contact the emergency services wherever overdose is suspected.</li> <li>• Individuals should be referred to an appropriate healthcare professional and/or advised on available treatment services if appropriate.</li> </ul> <p>Any action or referral should be noted in the individual's record or notes.</p>
<b>Action if naloxone is declined</b>	<ul style="list-style-type: none"> <li>• Provide with details on where they can access naloxone supply in the future. A list of current services can be accessed <a href="#">here</a>.</li> <li>• Document that the supply was declined, the reason and advice given in appropriate clinical records.</li> </ul>

### Description of treatment available under the PGD

<b>Name form and strength of medicine</b>	See individual medicine monographs.
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<b>Legal status</b>	<p>Medicines referred to in this PGD are all Prescription-only Medicines (POM).</p> <p>In accordance with the MHRA all medicines <b>supplied</b> under a PGD <b>must</b> 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.</p>
<b>Dosage/Maximum total dose</b>	See individual medicine monographs.
<b>Frequency of dose/Duration of treatment</b>	See individual medicine monographs.
<b>Maximum or minimum treatment period</b>	See individual medicine monographs.
<b>Route/Method of administration</b>	See individual medicine monographs.
<b>Quantity to be supplied</b>	See individual medicine monographs.
<b>Storage requirements</b>	See individual medicine monographs.

**The following information applies to both nasal and intramuscular products:**

<b>Follow-up (if applicable)</b>	<p>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.</p>
<b>Advice (Verbal)</b>	<p>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.</p> <p>The Key Information Sheet (<a href="#">Appendix 3</a>) will support this.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Encourage the person to carry the supply of naloxone with them at all times.</li> </ul>

	<ul style="list-style-type: none"> <li>• Ensure that the person has a basic understanding of overdose awareness, basic life support and can demonstrate how to administer naloxone.</li> <li>• Provide advice on other supportive strategies including harm reduction and overdose prevention.</li> <li>• Explain treatment and course of action.</li> <li>• On arrival of the ambulance they should advise ambulance staff of how the individual has responded and details of any adverse effects.</li> <li>• Highlight information included in the manufacturers Patient Information Leaflet. Where this is unavailable, or unsuitable, sufficient information should be given to the individual/parent/guardian in a language that they can understand. Resources are available from NHSG Health Information Resources team <a href="http://www.nhsghcpat.org">www.nhsghcpat.org</a></li> <li>• Advise on available <a href="#">services</a> for accessing further training and/or resupplies of used, lost or expired naloxone.</li> <li>• Individuals should be referred to an appropriate healthcare professional and/or advised on available treatment services if appropriate.</li> <li>• Any action or referral should be recorded in the individual's notes as appropriate.</li> <li>• Advice should be given on what to expect and what to do for major and minor reactions.</li> </ul> <p>Information on written advice specific to each product is listed in the individual medication monographs.</p>
<p><b>Identifying and managing possible adverse reactions</b></p>	<p>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:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Most common reactions include hypotension, hypertension, ventricular tachycardia.</li> <li>• Very rare or less common reactions include: - ventricular fibrillation (very rarely), cardiac arrest, hyperventilation, dyspnoea, pulmonary oedema, less commonly agitation, excitement and paraesthesia.</li> <li>• 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.</li> <li>• Symptoms of withdrawal in foetuses during pregnancy.</li> </ul>

	<p><b>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</b></p> <p><b>BNF/BNFC:</b>  <a href="#">BNF British National Formulary - NICE</a>  <a href="#">BNF for Children British National Formulary - NICE</a></p> <p><b>SmPC/PIL/Risk Minimisation Material:</b>  <a href="#">Home - electronic medicines compendium (emc)</a>  <a href="#">MHRA Products   Home</a>  <a href="#">RMM Directory - (emc)</a></p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System.  <a href="#">Yellow Card Scheme - MHRA</a></p>
<b>Facilities and supplies required</b>	<p>The following are to be available at sites where the medicine is to be supplied:</p> <ul style="list-style-type: none"> <li>• Appropriate storage facilities</li> <li>• An acceptable level of privacy to respect individual's right to confidentiality and safety</li> <li>• Access to a working telephone</li> <li>• Access to medical support (this may be via the telephone)</li> <li>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel</li> </ul> <p>A copy of this current PGD in print or electronically.</p> <p>Over labelled Nyxoid® and Prenoxad® for supply by PGD is stocked by ARI pharmacy and should be ordered through normal channels.</p>

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

<b>Professional qualifications</b>	Registered Nurses 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).
<b>Specialist competencies</b>	<p><b>Approved by the organisation as:</b></p> <ul style="list-style-type: none"> <li>• Competent to assess the individual's/person with parental responsibilities' capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent</li> <li>• Aware of current treatment recommendations and be competent to discuss issues about the medicine with the person</li> </ul>

	<ul style="list-style-type: none"> <li>• Having undertaken the appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD</li> <li>• Having completed the <a href="#">SDF e-learning package</a> or recognised Naloxone Take Home Programme Training</li> <li>• Having watched the videos on the administration of the two naloxone products available for supply <a href="http://www.nyxoid.com/uk">www.nyxoid.com/uk</a> and <a href="http://www.prenoxadinjection.com/video/admin.mp4">www.prenoxadinjection.com/video/admin.mp4</a></li> <li>• Competent to undertake supply of the medicine</li> <li>• Competent to work under this PGD.</li> </ul>
<b>Ongoing training and competency</b>	<p><b>All professionals working under this PGD must:</b></p> <ul style="list-style-type: none"> <li>• Have undertaken PGD module training on <a href="#">TURAS</a></li> <li>• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct</li> <li>• Have knowledge and familiarity of the following; <ul style="list-style-type: none"> <li>○ <a href="#">SmPC</a> for the medicine(s) to be supplied in accordance with this PGD.</li> </ul> </li> </ul>
<b>Responsibilities of professional manager(s)</b>	<p><b>Professional manager(s) will be responsible for;</b></p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.</p>

## Documentation

<b>Authorisation of supply</b>	<p>Nurses working within NHS Grampian can be authorised to supply the medicines specified in this PGD by their Nurse Manager or Substance Misuse Service Clinical Lead/Team Lead in NHS Grampian.</p> <p>Pharmacists working within NHS Grampian can be authorised to supply the medicines specified in this PGD by The Director of Pharmacy and Medicines Management.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (<a href="#">Appendix 1</a>).</p>
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	A Certificate of Authorisation ( <a href="#">Appendix 2</a> ) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.
<b>Record of supply</b>	<p>An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> <li>• Date and time of supply</li> <li>• Individual's name and CHI</li> <li>• Exclusion criteria, record why the medicine was not supplied (if applicable)</li> <li>• Record that valid consent to treatment under this PGD was obtained</li> <li>• The name, dose, form, route, batch number, quantity and expiry date of the medicine supplied</li> <li>• Advice given, including advice given if excluded or declined treatment under this PGD</li> <li>• Signature and name in capital letters of the healthcare professional who supplied the medicine</li> <li>• Record of any adverse effects (advise individual's GP/relevant medical practitioner).</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• NaSH – Sexual Health Electronic Patient Record</li> <li>• BadgerNet – Digital Maternity Notes</li> <li>• Individual's GP records if appropriate</li> <li>• Secondary Care Medical Notes</li> <li>• Individual service specific systems.</li> </ul>
<b>Audit</b>	All records of the medicine 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.
<b>References</b>	<p>Electronic Medicines Compendium  <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> Prenoxad® – Date of revision of text 09/07/21, accessed 23/08/21.</p> <p>Electronic Medicines Compendium  <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> Nyxoid® – Date of revision of text 28/06/21, accessed 23/08/21.</p>

	British National Formulary and British National Formulary for Children <a href="https://about.medicinescomplete.com/">https://about.medicinescomplete.com/</a> accessed 23/08/21.
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## 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:

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

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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.

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

**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

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

<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>

## Grampian Take Home Naloxone Key Points Sheet

### 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 50 milligrams 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 commands 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 2-3 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 NYXOID® NASAL SPRAY

- **DO NOT TEST THE SPRAY FIRST – THERE IS ONLY ONE SPRAY IN EACH NASAL SPRAY** (Box 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 Nyxoid® 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

Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®) .....	15
Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply).....	18

***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.***

<b>Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®)</b>	
<b>Indication</b>	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).
<b>Inclusion Criteria</b>	As per main PGD inclusion criteria and additionally:  Individuals aged 16 years or over.
<b>Exclusion Criteria</b>	As per main PGD exclusion criteria and additionally:  Individuals aged under 16 years.
<b>Precautions and Special Warnings</b>	<p>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.</p> <p>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.</p>
<b>Legal Status</b>	<p>Naloxone hydrochloride (Prenoxad®) is a Prescription-only Medicine (POM).</p> <p>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 <a href="#">Patient Information Leaflet</a>).</p>
<b>Dose/Maximum total dose</b>	<p>Individuals should be advised to administer Naloxone hydrochloride (Prenoxad®) as follows;</p> <ul style="list-style-type: none"> <li>A single dose (400micrograms or 0.4mL) of naloxone should be administered by intramuscular injection into the thigh or upper arm.</li> </ul> <p>Each syringe contains five doses which are clearly marked.</p>
<b>Frequency of dose/Duration of treatment</b>	<p>Individuals should be advised:</p> <ul style="list-style-type: none"> <li>If there is no response after 2-3 minutes a further dose should be administered. This should be repeated until either:</li> </ul>

Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®)	
	<ul style="list-style-type: none"> <li>○ The person regains consciousness or</li> <li>○ All 5 doses have been used (further doses may be given if available) or</li> <li>○ The emergency services arrive and take over.</li> </ul> <p>Refer to current edition of the BNF and SmPC for further information. Information can also be found on the Prenoxad® website.</p> <p>Healthcare professionals should discuss where naloxone fits in the basic life support process.</p> <p><b>Unresponsive and breathing normally.</b> The casualty should be placed in the recovery position and naloxone administered every 2-3 minutes as required.</p> <p><b>Unresponsive and not breathing normally.</b> Cardiopulmonary resuscitation (CPR) should be started. Naloxone should be administered following the 1st cycle of CPR and every 3 cycles thereafter.</p>
<b>Maximum or minimum treatment period</b>	See Frequency of dose/Duration of treatment section above.
<b>Route/Method of Administration</b>	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.
<b>Quantity to be supplied</b>	<p>People at risk of future opioid overdose can receive:</p> <ul style="list-style-type: none"> <li>• One naloxone hydrochloride (Prenoxad®) kit for intramuscular use.</li> <li>• 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.</li> <li>• Two different formats of naloxone hydrochloride may be supplied in one transaction, e.g. one pack of Nyxoid® and one Prenoxad® kit.</li> </ul>
<b>Potential Adverse Reactions</b>	<p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects.</p> <p>The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <p>Dizziness, headache, hypertension, hypotension, nausea, tachycardia, vomiting.</p>

<b>Naloxone Hydrochloride Solution for Injection 2mg/2mL (Prenoxad®)</b>	
<b>Advice</b>	<p>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 <a href="http://www.nhsghpcat.org">www.nhsghpcat.org</a>).</p> <p>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 <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or <a href="http://www.mhra.gov.uk/spc-pil/index.htm">www.mhra.gov.uk/spc-pil/index.htm</a></p>
<b>Follow up (if applicable)</b>	<p>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</p>
<b>Storage</b>	<p>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.</p> <p>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.</p>



Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply)	
<b>Indication</b>	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).
<b>Inclusion Criteria</b>	As per main PGD inclusion criteria and additionally:  Individuals aged 14 years and over
<b>Exclusion Criteria</b>	As per main PGD exclusion criteria and additionally:  Individuals aged under 14 years.
<b>Precautions and Special Warnings</b>	<p>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.</p> <p>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.</p>
<b>Legal Status</b>	<p>Naloxone hydrochloride (Nyxoid®) is a Prescription-only Medicine (POM).</p> <p>In accordance with the MHRA all medicines <b>supplied</b> under a PGD <b>must</b> 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.</p>
<b>Dose/Maximum total dose</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• The nasal spray should not be primed or tested prior to use as it only contains a single dose of naloxone.</li> <li>• The contents of a nasal spray (1.8mg) should be sprayed into the casualty's nostril.</li> </ul>
<b>Frequency of dose/Duration of treatment</b>	<p>Individuals should be advised that</p> <ul style="list-style-type: none"> <li>• If there is no response after 2-3 minutes a second nasal spray should be sprayed into the other nostril.</li> <li>• If the person does not respond to two doses, further doses may be given (if available).</li> </ul>

<b>Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply)</b>	
	<p>Healthcare professionals should discuss where naloxone fits in the basic life support process.</p> <p><b>Unresponsive and breathing normally.</b> The casualty should be placed in the recovery position and naloxone administered every 2-3 minutes as required.</p> <p><b>Unresponsive and not breathing normally.</b> Cardiopulmonary resuscitation (CPR) should be started. Naloxone should be administered following the 1st cycle of CPR and every 3 cycles thereafter.</p> <p>Refer to current edition of the BNF and SmPC for further information. More information, including a video, can be found on the Nyxoid® website <a href="https://nyxoid.com/uk">https://nyxoid.com/uk</a></p>
<b>Maximum or minimum treatment period</b>	See Frequency of dose/Duration of treatment section above.
<b>Route/Method of Administration</b>	The dose should be administered into one nostril with repeated doses being sprayed into alternate nostrils
<b>Quantity to be supplied</b>	<p>People at risk of future opioid overdose can receive:</p> <ul style="list-style-type: none"> <li>• One pack of naloxone hydrochloride (Nyxoid®) nasal spray</li> <li>• An additional pack of naloxone hydrochloride (Nyxoid®) nasal spray to hold as a spare supply if required, e.g. splits time between family home and other property</li> <li>• Two different formats of naloxone hydrochloride may be supplied in one transaction, e.g. one pack of Nyxoid® and one Prenoxad® kit.</li> </ul>
<b>Potential Adverse Reactions</b>	<p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects.</p> <p>The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <p>Dizziness, headache, hypertension, hypotension, nausea (very common), tachycardia, vomiting.</p>
<b>Advice</b>	<p>Individuals should also be issued with a Nyxoid® patient information leaflet (orderable from NHS Grampian Health Information Resources Service <a href="http://www.nhsghpcat.org">www.nhsghpcat.org</a>).</p> <p>The Nyxoid leaflet can also be printed from the following link: <a href="http://www.medicines.org.uk/emc/rmm/1278/Document">www.medicines.org.uk/emc/rmm/1278/Document</a></p>

<b>Naloxone Hydrochloride Dihydrate 1.8mg Per Nasal Spray (Nyxoid®) (Supply)</b>	
	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 <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or <a href="http://www.mhra.gov.uk/spc-pil/index.htm">www.mhra.gov.uk/spc-pil/index.htm</a>
<b>Follow up (If applicable)</b>	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.
<b>Storage</b>	Do not freeze