

Service	Naloxone (Prenoxad) provision
Authority Lead	Jane Sunter, Public Health Strategic Manager – Living Well, Ageing Well
Provider Lead	
Period	1 April 2024 to 31 March 2025

1. Purpose and Scope

1.1 Background

Drug related deaths are preventable. Pharmacies have a major role in improving care, reducing harm and preventing death in people who use drugs.

The RPS recommends that:¹ *Naloxone must be available from every community pharmacy for supply to people who use drugs, family, healthcare professionals, and carers. Naloxone should also be kept in first aid boxes for emergency use in any clinical setting, and staff trained to use it, where people who use drugs attend. Pharmacy teams in those locations must be among the staff trained to use it.*

Naloxone supply is a critical intervention, particularly with the increasing use of potent synthetic opioids.² Local authorities that commission drug treatment services, are responsible for making take-home naloxone more readily available and from a wider range of outlets.³

1.2 Naloxone (Prenoxad) Supply⁴

1.2.1 The Legislation⁵

Naloxone injection is a POM, however following legislative changes in 2015 it can be supplied without a prescription by persons employed or engaged in the provision of drug treatment services (provided by, on behalf of or under arrangements with a body such as a local authority) for the purposes of saving life in an emergency. Therefore, this supply can be to:

- an individual currently, or with a history of, using opioids
- a carer, family member or friend liable to be on hand in case of overdose

Drug services commissioned by a local authority or the NHS that can supply naloxone include but may not be limited to:

- specialist drug treatment services
- primary care drug services
- a pharmacy providing supervised consumption of opioid substitute medication

1.2.2 What is Naloxone?

Naloxone is the emergency first aid response to an opioid overdose.

Naloxone itself has no psychoactive properties and so has no intoxicating effects or misuse potential.

Naloxone will quickly and temporarily reverse life-threatening effects of an opioid overdose (such as depressed breathing) for around 20 minutes (and up to 1 hour). Because the effect is only temporary, it is essential that an ambulance is also called.

Prenoxad injection is licensed specifically for use in the community and comes in a pre-filled syringe (connect the needle) containing 5 marked doses of 400 microgram naloxone.

The recommended intramuscular dose is 400 micrograms initially, with further 400 microgram doses given incrementally every 2-3 minutes until an effect is noted or the ambulance arrives.

It is given incrementally to reduce the chance of a bad withdrawal when that person regains consciousness.

¹ Improving care, reducing harm and preventing death in People Who Use Drugs: Pharmacy's role. RPS 2021.

<https://www.rpharms.com/recognition/all-our-campaigns/policy-a-z/drug-deaths-and-the-role-of-the-pharmacy-team>

² Potent synthetic opioids implicated in heroin overdoses and deaths. NPSA. Published 26/07/23.

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103236>

³ Guidance for local areas on planning to deal with potent synthetic opioids. OHID. Updated 31/07/23.

<https://www.gov.uk/government/publications/fentanyl-preparing-for-a-future-threat/guidance-for-local-areas-on-planning-to-deal-with-fentanyl-or-another-potent-opioid>

⁴ Take-home naloxone for opioid overdose in people who use drugs: Advice for local authorities on providing more naloxone to reduce overdose deaths from heroin and other opioids. PHE. Published 01/07/17.

www.gov.uk/government/publications/providing-take-home-naloxone-for-opioid-overdose

⁵ Guidance: Widening the availability of naloxone. PHE, DHSC, MHRA. Updated 18/02/19.

www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone

1.3 Aims and Objectives

The aim of the service is to:

- Provide a naloxone (Prenoxad) supply service to clients and the wider community which will help to support a reduction in accidental deaths from opioid overdose.

The objective of the service is to:

- Reduce the possibility of accidental poisoning and overdose from opioids.

2. Service

2.1 Access to the Service

To ensure county-wide access to naloxone supply, all community pharmacies within the County Durham area will be given the opportunity to provide this service, however pharmacies providing either the supervised consumption and / or the needle exchange service will be best placed to provide naloxone (Prenoxad) supply.

2.1.1 Inclusion Criteria

The person receiving the supply of naloxone (Prenoxad) resides in County Durham, is aged 18 and over, and is either:

- an individual currently, or with a history of, using opioids.

or:

- a carer, family member, or friend liable to be on hand in case of overdose (Note: It is legal for a drug service to provide a family member / friend / carer of an opioid user with naloxone without the express permission of the individual who is using the opioid, if it is being supplied to save life in an emergency⁶).

2.1.2 Exclusion Criteria

- Persons under the age of 18 years of age.
- Persons not resident in County Durham.
- Where the individual at risk has a known allergy to naloxone.

2.2 General Pharmacy Contractor Responsibilities

- To have a suitable SOP in place to cover all processes involved with this service. This should be readily available to all members of staff.
- To have a designated lead pharmacist or lead registered technician at the pharmacy who will be responsible for the day to day running of this service.
- To ensure that all pharmacy staff have completed the necessary training requirements (Section 3.1).
- To ensure that the appropriate indemnity arrangements are in place.
- To ensure prompt data entry onto PharmOutcomes once each naloxone (Prenoxad) supply is made.

2.3 Naloxone (Prenoxad) Supply

There are no labelling requirements for the supply of naloxone (Prenoxad) when it is made for the purposes of saving life in an emergency.

The SmPC of Naloxone (Prenoxad) injection⁷ states that:

Prenoxad Injection may only be made available once the prescriber has assessed the suitability and competence of a client or representative to administer naloxone in the appropriate circumstances.

i.e. all those receiving a supply of naloxone (Prenoxad) should receive information on a basic awareness of opioid overdose, basic life-support and naloxone use (as described in Appendix 1).

The lead pharmacist or lead registered technician at the pharmacy will ensure that:

- Pharmacy staff have undertaken the necessary training to provide supplies of naloxone (Prenoxad) (Section 3.1).
- Pharmacy staff are aware of how to issue naloxone (Prenoxad) (Appendix 1) and the data entry requirements on PharmOutcomes (Appendix 2).
- The pharmacy routinely stocks Prenoxad (with a minimum stock level held of two).

⁶ www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone

⁷ <https://www.medicines.org.uk/emc/product/3054>. Updated 02/06/21

- The pharmacy can signpost to or supply the 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms> (supplies can be requested at <http://www.prenoxadinjection.com/drug/training.html>).

To supply naloxone (Prenoxad) the trained pharmacy staff member should:

- Check that the person receiving the supply is 18 years of age or over, and resides in County Durham.
- Check that the individual at risk has no known allergies to Prenoxad injection.
- Deliver the information as recommended in Appendix 1 and by ideally providing or signposting to 'Prenoxad Injection Clients Guide'.

The following details should be recorded on PharmOutcomes (Appendix 2) including:

- Person initials
- Age
- First part of post code
- Whether the supply is to an individual at risk or a family/friend/carer
- BN and expiry date of Prenoxad
- Confirmation of information provided
- Details of pharmacy staff member providing the supply

3. Clinical Governance

Pharmacy contractors are required to operate to appropriate standards of clinical governance. The contractor will comply with the GPhC standards for pharmacy premises at www.pharmacyregulation.org/standards/standards-registered-pharmacies

3.1 Education and Training

It is the duty of the contractor to ensure that the service is delivered by staff who have the necessary competence and training for this service.

The contractor should ensure that a lead pharmacist or lead registered technician has completed the required mandated training which is to:

1. View the following information on the Prenoxad website:

Read the brief information:

- When and how to give Prenoxad injection (6 sections) at www.prenoxadinjection.com/drug/when_and_how.html

And view the 5 short videos at www.prenoxadinjection.com/drug/how-to.html:

- How to respond when someone is unconscious and unresponsive
- How to respond to suspected opioid overdose
- How to put someone into the recovery position
- How to perform CPR
- How to inject Prenoxad Injection

2. Complete the CPPE endorsed 'Naloxone saves lives' e-assessment at <https://www.ap-elearning.org.uk/>. The notional learning time is 1 hour. On completion a Certificate of Completion is issued.

The lead pharmacist / registered technician should be assured that all staff are competent to deliver the service and will complete the required mandated training which is to:

1. View the following information on the Prenoxad website:

Read the brief information:

- When and how to give Prenoxad injection (6 sections) at www.prenoxadinjection.com/drug/when_and_how.html

And view the 5 short videos at www.prenoxadinjection.com/drug/how-to.html:

- How to respond when someone is unconscious and unresponsive
- How to respond to suspected opioid overdose
- How to put someone into the recovery position
- How to perform CPR
- How to inject Prenoxad Injection

Non-mandated training:

View the local online training signposted to on the CPNEC website at <https://www.cpniec.org.uk/> which describes how to interact with clients and how to run a successful service.

For 2024 – 25, a PharmOutcomes Declaration needs to be completed for each staff member accessing the claims template (Appendix 3).

All staff are also expected to keep up to date with guidance / service changes and to assess their competence on an ongoing basis.

3.2 Incident Reporting

- A summary of incidents or complaints should be reported to the service commissioner Jane Sunter (email: jane.sunter@durham.gov.uk) upon request. The contractor will inform the commissioner with a summary of the incident/complaint(s) and an action plan for ensuring any such incidents/complaints can be avoided in the future, and how lessons have been learnt.

4. Payment

Payment claims are made via PharmOutcomes. All fields must be complete and accurate. Any inaccurate claims may be investigated on a quarterly basis. In the event of over claims being made, the Local Authority has the right to reclaim all monies.

Information on naloxone (Prenoxad) supply should be entered within 2 months of supply.

Public Health will generate the monthly claims from PharmOutcomes for all pharmacies on the 15th of every month and send the report to DCC Finance for payment. There will be no requirement for pharmacists to send invoices. Any queries relating to payment must be made to publichealth@durham.gov.uk.

Naloxone (Prenoxad) supply

- Once the pharmacy is ready to deliver the service, the pharmacist / registered technician service lead should complete the service declaration on PharmOutcomes for 2024-25 for a set-up fee of £50 ex VAT plus the cost of the minimum stock holding of two Prenoxad injections (cost in accordance with the Drug Tariff price plus 20% VAT).
- Pharmacies will receive a payment for the product cost, plus £8 ex VAT for each supply of Prenoxad injection.

5. Termination of Agreement

Any pharmacy contractor wishing to terminate this agreement must give 3 month notice prior to termination. Notice of termination must be emailed to:

Jane Sunter

Public Health Strategic Manager – Living Well, Ageing Well

Public Health Team

Durham County Council

Green Lane Council Offices

Spennymoor

DL16 6JQ

Email: jane.sunter@durham.gov.uk

Durham County Council and Public Health may also terminate this agreement with 3 months written notice.

Appendix 1: How to supply naloxone (Prenoxad)

Lessons learnt from successful community pharmacy supply models:

- Proactively offer naloxone as part of an opioid collection / supervised consumption or a needle exchange: Have it in your hand as you offer it.
- Deliver this intervention as you would an OTC supply: A quick 5-minute intervention, giving key points only (see recommendations below).
- Ideally back up by signposting to or supplying the 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms>⁸: Or say that there's a leaflet in the pack.

Recommendations for a conversation during a needle exchange or an opioid collection / supervision:

- Do you have a naloxone kit? This is an emergency first aid response to an opioid overdose (show the box).
- Overdose deaths are soaring and we are trying to stop that. So, lots of people are carrying naloxone in case they see someone overdose. It's free, it's easy to use. I'd like to give you one to take away.
- There's a leaflet in the kit which explains how to use it. You need to attach the needle. There are 5 doses in the kit, inject one dose at a time (down the black lines on the needle) into the thigh 2-3 minutes apart until they start to respond. This is to avoid bringing people round in a bad withdrawal.
- It's vital to always call an ambulance (even if the person is breathing) since naloxone will only reverse the effects of the opioid overdose for around 20 minutes.
- The leaflet also explains what to do if the person isn't breathing, but the emergency services call handler will talk you through what to do.

⁸ Supplies can be requested at <http://www.prenoxad injection.com/drug/training.html>

Appendix 2: PharmOutcomes claims template

Date of supply (record on PharmOutcomes within 2 months of the date of supply):

Person initials:

Person age (aged 18 and over):

Person first part of post code (resides in County Durham):

Is the supply to:

Person who uses substances

OR

Family / friend / carer of person using substances

Recommended information delivered?:

(Using the advice in Appendix 1 and by ideally providing or signposting to 'Prenoxad Injection Clients Guide').

Yes

No

Number of packs supplied:

BN:

Expiry date:

Name of staff member supplying:

Role of staff member supplying:

Appendix 3: PharmOutcomes Declaration

Naloxone (Prenoxad) Supply Service Declaration 2024-25

The lead pharmacist / registered pharmacy technician has confirmed that:

Training

- They have completed the mandated training specified in the service specification.
- They will ensure that all other staff complete the mandated training specified in the service specification.
- They will keep up to date with guidance / service changes and cascade this to other members of staff providing the service.

Supply

- The pharmacy stocks Prenoxad injection (with a minimum stock level of two).
- The pharmacy can signpost to or supply the Prenoxad Injection Clients Guide.
- All staff are aware of the data collection requirements on PharmOutcomes.