

Service	Naloxone (Prenoxad) provision
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Provider Lead	
Period	1st April 2022 to 31st March 2023

1. Purpose and Scope

1.1 National Picture

Drug deaths have been rising year-on-year in Great Britain. Deaths from drug poisoning in England, Scotland, and Wales have reached a record high.

In England and Wales, two-thirds (2,996) of drug poisoning deaths in 2020 were related to drug misuse and addiction, the highest number since records began in 1993.

Covid-19 has impacted on the nation's mental health and wellbeing, but the effect of isolation, financial insecurity and fear has hit many of those who were already vulnerable, including people with a history of drug misuse and addiction.

Every drug related death is preventable. Pharmacists have a major role in improving care, reducing harm and preventing death in people who use drugs.

With drug-related deaths continuing to increase, there continues to be a national focus on increasing the availability of naloxone:

- The 2021 RPS report *Improving care, reducing harm and preventing death in People Who Use Drugs: Pharmacy's role*¹ recommends that: *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.*
- In 2021, the Government consulted on expanding access to naloxone by expanding the list of services and individuals that can give it out without a prescription or other written instruction (e.g. supply by homelessness or rough sleeping support services).²

1.2 Local Picture

County Durham has some of the greatest health needs in England. Substance misuse is strongly associated with poverty and deprivation and impacts on substance misuse related deaths, blood borne virus infections, crime, child protection issues, domestic abuse and mental health. In County Durham the legacy of the loss of ready employment, especially male employment through mining and other industries has left many communities vulnerable to the effects of substance misuse. These communities are not concentrated in specific areas across the county but spread among a diverse range of areas including towns and small villages.³

1.3 National Guidance for Naloxone (Prenoxad) Supply⁴

1.3.1 The Legislation⁵

Naloxone injection is a prescription only medicine (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; in the course of provision of lawful drug treatment services; and for the purposes of supplying naloxone where it is required for the purpose 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

¹ <https://www.rpharms.com/recognition/all-our-campaigns/policy-a-z/drug-deaths-and-the-role-of-the-pharmacy-team>

² <https://www.gov.uk/government/consultations/consultation-on-expanding-access-to-naloxone/consultation-on-expanding-access-to-naloxone>

³ <https://www.durhaminsight.info/living-well/substance-misuse/>

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 2017

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

⁵ Guidance: Widening the availability of naloxone. PHE, DH, MHRA. Updated February 2019.

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

Drug services commissioned by a local authority or the NHS include:

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

1.3.2 What is Naloxone?

Naloxone is an emergency antidote to opioid overdose. In the event of a suspected opioid overdose naloxone can temporarily reverse the life-threatening effects of an overdose of opioids such as depressed breathing, for approximately 20-30 minutes.

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

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

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.

1.4 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

Note: Before the service can commence, the provider must sign a Public Health contract. Contact Adult and Health Services Commissioning (Email: AHS.Commissioning@durham.gov.uk).

2.1 Service Description

This is a locally commissioned service within the community pharmacy contractual framework commissioned by Durham County Council, through Public Health to meet the needs of the population of County Durham.

2.2 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.

2.2.1 Inclusion Criteria

The person requesting 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.

The SmPC of Naloxone (Prenoxad) injection⁶ 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 be able to demonstrate a basic awareness of opioid overdose, basic life-support and naloxone use.

Under the Regulations, 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 emergency⁷.

Consider asking the family member / friend / carer if they intend informing the individual at risk of opioid overdose that they have a supply of naloxone injection. However, balance this against the

⁶ <https://www.medicines.org.uk/emc/product/3054>. Updated 2/6/21

⁷ www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone

fact that legally a 3rd party supply can be made to save a life in an emergency and that naloxone has a good safety profile when administered in the doses contained in Prenoxad injection (i.e. administering a relatively small dose of naloxone, then providing further small doses as needed in a graduated manner).

2.2.2 Exclusion Criteria

- Persons under the age of 18 years of age.
- Persons unable to demonstrate a sufficient knowledge on the use of naloxone (Prenoxad) to be safely given a supply.
- Persons who have not consented to receiving a supply.
- Where the individual at risk has a known allergy to naloxone.

2.3 General Pharmacy Responsibilities

- To have in place suitable Standard Operating Procedures (SOPs) to cover all processes involved in service delivery. Company policies are acceptable where they reflect the principles of the scheme. The SOPs should be readily available to all members of staff and in particular locum staff.
- To have a designated named lead pharmacist or lead registered technician at the pharmacy who will be responsible for the day to day running of this service and will ensure all locums are informed.
- To ensure that the appropriate indemnity arrangements are in place.
- To promptly enter data onto PharmOutcomes once each naloxone (Prenoxad) supply is made.

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

- Pharmacists and the lead registered technician (as applicable) have undertaken the necessary training to provide new supplies of naloxone (Prenoxad) upon request to adults aged 18 and over who have never previously received naloxone (Prenoxad) (see section 3.1.1).
- All pharmacy staff have undertaken the necessary training to provide repeat supplies upon request to adults aged 18 and over who have previously received naloxone (Prenoxad) (see section 3.1.2).
- All staff are aware of how to counsel people requesting naloxone (Prenoxad), the necessary paperwork to complete, and the data entry requirements on PharmOutcomes.
- The pharmacy routinely stocks Prenoxad (with a minimum stock level held of two).
- The pharmacy has a supply of customer supply records (see Appendix 1 and 2) and access to the company information 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms>.

2.4 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.

2.4.1 Supplying Naloxone (Prenoxad) to a Person Who Has Previously Never Received a Supply

Naloxone (Prenoxad) injection may only be supplied once the pharmacist or lead registered technician supplying it has:

- Checked that the person requesting the supply is 18 years of age or over and resides in County Durham.
- Checked that the individual at risk has no known allergies to naloxone.
- Ensured that individuals receiving a supply of naloxone (Prenoxad) have a basic awareness of and have received information on opioid overdose, basic life-support and naloxone use.
- Received the necessary signed consent (see Appendix 1) and provided the required accompanying information (the 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms>).

The person receiving the supply should receive a brief intervention on basic life support, signs and symptoms of opioid overdose, and how to assemble and safely administer naloxone (Prenoxad) using the training check list on the customer naloxone supply record

(see Appendix 1: all the information in this checklist is also covered the 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms>).

All relevant details should be recorded on the customer naloxone supply record (see Appendix 1) including:

- Person's details
- Whether the supply is to an individual at risk or a family/friend/carer
- BN and expiry date of Prenoxad
- Details of pharmacist or lead registered technician providing the intervention and the supply

Other factors to record:

- Is the individual at risk of opioid overdose pregnant?
- Does the individual at risk have any heart, renal or liver problems?

If the answer is yes to either of these a naloxone (Prenoxad) supply can still be made, and the person advised that naloxone (Prenoxad) can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced.

2.4.2 Issuing a Re-supply of Naloxone (Prenoxad)

Naloxone (Prenoxad) injection may only be supplied once the pharmacy staff member supplying it has:

- Checked that the person requesting the supply is 18 years of age or over and resides in County Durham.
- Checked that the individual at risk has no known allergies to naloxone.
- Ensured that individuals receiving a supply of naloxone (Prenoxad) have a basic awareness of and have received information on opioid overdose, basic life-support and naloxone use.
- Received the necessary signed consent (see Appendix 2) and provided the required information to that person (i.e. a copy of the 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms>).

All relevant details should be recorded on the customer naloxone re-supply record (see Appendix 2) including:

- Person's details
- Whether the supply is to an individual at risk or a family/friend/carer
- Reason for repeat supply e.g. used for overdose, lost or damaged pack
- BN and expiry date of Prenoxad
- Details of the staff member providing the information and the supply

Other factors to record:

- Is the individual at risk of opioid overdose pregnant?
- Does the individual at risk have any heart, renal or liver problems?

If the answer is yes to either of these a naloxone (Prenoxad) supply can still be made, and the person advised that naloxone (Prenoxad) can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced.

3. Clinical Governance

Pharmacy providers are required to operate to appropriate standards of clinical governance. The pharmacy 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 provider to ensure that the service is delivered by staff who have the necessary competence and training in this service.

A lead pharmacist or a lead registered technician should be assured that all staff (including support staff and locum pharmacists) are adequately trained to meet the requirements of the service.

For 2022 – 23 training will be declared by a lead pharmacist or a lead registered technician by

completion of a PharmOutcomes Declaration (see Appendix 3 for the template PharmOutcomes Declaration).

All pharmacy staff involved in the service are expected to read the service Annual Update Briefing 2022-23 and consider any further training needs.

Staff are also expected to keep up to date with guidance / service changes (via information circulated on PharmOutcomes) and to assess their competence on an ongoing basis.

3.1.1 Pharmacist or the lead registered technician training

All initial supplies of naloxone (Prenoxad) made to adults aged 18 and over who have never previously received naloxone (Prenoxad) must be made by a trained pharmacist or the trained lead registered technician.

Training will cover⁸

- Overdose risks: polydrug (especially benzodiazepines) and alcohol use, getting older, post-detox/rehab/prison.
- What naloxone can and can't do: it just reverses opioid overdose. If someone has also taken too many other drugs or too much alcohol, it won't reverse these effects.
- How to identify an opioid overdose: lack of consciousness, shallow or no breathing, 'snoring', and blueing of the lips and fingertips.
- How to use naloxone.
- Steps to take in responding to an overdose.

Pharmacists / a lead registered technician intending to supply naloxone (Prenoxad) must:

View the following information on the Prenoxad website:

Read the brief information at:

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

Note: The above information is also available at

<https://www.medicines.org.uk/emc/product/3054/rmms> in the:

- Prenoxad Injection Issuers Guide
- Prenoxad Injection Client's Guide

And view the 5 videos (2-3 minutes each) 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

Complete the CPPE endorsed 'Naloxone saves lives' e-assessment at

<https://www.ap-elearning.org.uk/> which will enable pharmacists / the lead registered technician to:

- Understand drug related deaths and risks, and how to recognise the signs and symptoms of an overdose
- Know what to do and what not to do in the event of an overdose
- Be aware of what naloxone is and how it can help
- Be familiar with naloxone provision in the UK
- Understand the importance of training people in the use of naloxone and what should be included in training

The notional learning time is 1 hour. On completion a Certificate of Completion is issued.

3.1.2 Staff Training

All repeat supplies of naloxone (Prenoxad) made to adults aged 18 and over who have

⁸Take-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 2017 www.gov.uk/government/publications/providing-take-home-naloxone-for-opioid-overdose

previously received naloxone (Prenoxad) can be made by any member of trained pharmacy staff.

All staff intending to re-supply naloxone (Prenoxad) must view the following information on the Prenoxad website:

Read the brief information at:

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

Note: The above information is also available at <https://www.medicines.org.uk/emc/product/3054/rmms> in the:

- Prenoxad Injection Issuers Guide
- Prenoxad Injection Client's Guide

And view the 5 videos (2-3 minutes each) 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

3.2 Incident Reporting

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

4. Payment

Payment claims are made via PharmOutcomes. All fields must be complete and accurate. Any inaccurate claims (e.g. claiming a supervision fee when the pharmacy is closed) will 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 pharmacist service lead / lead registered technician completes the service declaration on PharmOutcomes for 2022-23 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) will be paid to the pharmacy via PharmOutcomes.
- Pharmacies will receive a payment for the product cost, plus £8 ex VAT for a supply of Prenoxad injection made to a person who has not received the necessary training and naloxone (Prenoxad) supply before (this supply must be made by trained pharmacists or the lead trained registered technician - see Section 3.1 Education and Training).
- Pharmacies will receive a payment for the product cost, plus £4 ex VAT for a re-supply of naloxone (Prenoxad) injection made to a person who has previously received a supply (and hence the necessary training) (this supply can be made by any member of the pharmacy team – see Section 3.1 Education and Training).

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
County Hall
Durham
DH1 5UJ
Email: jane.sunter@durham.gov.uk

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

In addition, there is a fixed overall budget for this service. Public Health will monitor spend against this budget and, in the unlikely event that the budget becomes overspent, will notify all providers to cease service provision before year end, with a 1 month notice period.

Appendix 1:

New supply of naloxone (Prenoxad brand) (to a person who has previously never received a supply)



Person supplied:

Person name:

DoB:

Address:

..... Postcode

Contact telephone number: (in case of a batch recall)

Is the person (delete as appropriate): Individual at risk? Family / friend / carer?

Does the individual at risk have any previous known history of an allergy to naloxone?

No Yes (If the answer is yes a supply cannot be made)

Is the individual at risk of opioid overdose pregnant?

No Yes (If the answer is yes a naloxone supply can still be made and the person advised that naloxone can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced)

Does the individual at risk have any heart, renal or liver problems?

No Yes (If the answer is yes a naloxone supply can still be made and the person advised that naloxone can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced)

Person declaration:

- I confirm that I have been supplied with naloxone (Prenoxad brand), have been given and understand the relevant information about when and how to use naloxone, and understand the need for basic life support and to call an ambulance.
- I accept that my information will be stored in the pharmacy for 6 + 1 years for audit purposes and in accordance with The Data Protection Act 2018. I acknowledge that anonymised data will be shared with the Public Health team at Durham County Council for payment and service evaluation purposes.

Print name:

Signature:

Date:

Naloxone (Prenoxad brand) issued:

BN:

Expiry date:

Pharmacist declaration:

I can confirm that this person receiving their first supply of naloxone has demonstrated an understanding of the checklist information contained on the back of this form¹ and has been provided with the relevant public information materials.

Pharmacist
name:

Pharmacist
signature:

Date:

Appendix 1 cont':

Checklist for new supply of naloxone

Discuss the signs and symptoms of suspected opioid overdose including:

- Loss of consciousness; pinpoint pupils; not breathing normally (including snoring); pale skin colour, bluish tinge to lips and fingertips.

Highlight the key facts with naloxone

- Opioid drugs include: Heroin, methadone, morphine, fentanyl, tramadol, buprenorphine.
- It just reverses opioid overdose: If someone has also taken too many other drugs or too much alcohol, it won't reverse these effects.
- It is short acting: The effects of naloxone will wear off after 20-30 minutes and the possibility that overdose may return.

Briefly describe how to put the person into the recovery position

Briefly describe how to perform chest compressions and rescue breaths if the person is not breathing

- 30 compressions followed by 2 rescue breaths.

Demonstrate how to assemble naloxone (Prenoxad brand) injection

Discuss how to administer the naloxone (Prenoxad brand) injection

- If the person is not breathing, an ambulance should be called immediately. Give 30 chest compressions and 2 rescue breaths, then administer the first dose (0.4ml) of Prenoxad injection into the outer thigh or upper arm (through clothes if necessary). Repeat three cycles of 30 chest compressions and 2 rescue breaths, followed by one dose (0.4ml) of Prenoxad injection until the person begins breathing or the ambulance arrives.
- If the person is unconscious and breathing, an ambulance should be called after the person has been moved into the recovery position and the first dose (0.4ml) of Prenoxad injection administered. Repeat one dose (0.4ml) of Prenoxad injection into the outer thigh or upper arm (through clothes if necessary) every 2-3 minutes until the person regains consciousness or the ambulance arrives.

Emphasise the importance of staying with the person

- The person should not be left alone.
- Police do not now routinely attend when an ambulance is called.
- The person should not be allowed to use any other drugs if they regain consciousness: The person may wish to take more opioid drugs to negate the effect of withdrawal that naloxone will cause (taking more opioid drugs will increase the risk of further overdose and should be strongly discouraged. Withdrawal effects will be short lived as naloxone will begin to wear off after 20 – 30 minutes).

Appendix 2:

Naloxone (Prenoxad brand) re-supply (to a person who has previously received a supply)



Person supplied:

Person name:

DoB:

Address:

..... Postcode

Contact telephone number: (in case of a batch recall)

Is the person (delete as appropriate): Individual at risk? Family / friend / carer?

Does the individual at risk have any previous known history of an allergy to naloxone?

No Yes (If the answer is yes a supply cannot be made)

Is the individual at risk of opioid overdose pregnant?

No Yes (If the answer is yes a naloxone supply can still be made and the person advised that naloxone can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced)

Does the individual at risk have any heart, renal or liver problems?

No Yes (If the answer is yes a naloxone supply can still be made and the person advised that naloxone can be administered for the purposes of saving a life. The importance of calling an ambulance should be reinforced)

Person declaration:

I confirm that I have been:

- Previously supplied with naloxone (Prenoxad brand) and have received and understood the necessary information on when and how to use naloxone, the need for basic life support and to call an ambulance.
- Issued with a re-supply of naloxone (Prenoxad brand) on this occasion and have been given the relevant information on when and how to use naloxone, basic life support and the need to call an ambulance.

I accept that my information will be stored in the pharmacy for 6 + 1 years for audit purposes and in accordance with The Data Protection Act 2018. I acknowledge that anonymised data will be shared with the Public Health team at Durham County Council for payment and service evaluation purposes.

Print name:

Signature:

Date:

Naloxone (Prenoxad brand) issued:

BN:

Expiry date:

Reason for re-supply

Used on self

Used on other

Lost or damaged kit

Expired kit

Other

Staff detail:

Staff name:

Signature:

Date:

Appendix 3: PharmOutcomes Declaration

Naloxone (Prenoxad) Supply Service Declaration 2022-23

Core requirement

I can confirm that the contractor has signed the Public Health pharmacy contract (for any enquiries email AHS.Commissioning@durham.gov.uk).

Service specific requirements

As the lead pharmacist / registered pharmacy technician I can confirm that:

Training

- All pharmacists providing this service will complete the specified training and obtain their Certificates of Completion for the e-assessment at <https://www.ap-elearning.org.uk/> within 3 months of completing this declaration.
- If applicable, a lead registered technician will complete the specified training and obtain their Certificates of Completion for the e-assessment at <https://www.ap-elearning.org.uk/> within 3 months of completing this declaration.
- All pharmacy staff providing re-supplies will complete the specified training within 3 months of completing this declaration.
- I will keep up to date with guidance / service changes (via information circulated on PharmOutcomes), 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 has supplies of the necessary customer materials (naloxone supply records - tear off pads from the Council) and patient information (access to 'Prenoxad Injection Clients Guide' at <https://www.medicines.org.uk/emc/product/3054/rmms>).
- People requesting naloxone (Prenoxad) will be aged 18 and over, resident in County Durham, and either be requesting it for themselves or as carer, family member or friend liable to be on hand in case of overdose.
- Trained pharmacists or the trained lead registered technician will supply naloxone (Prenoxad) injection to a person who has previously never received a supply, using the relevant customer materials and following completion of the customer naloxone supply record.
- Any trained member of staff may issue a re-supply of naloxone (Prenoxad) using the relevant customer materials and following completion of the customer naloxone (Prenoxad) re-supply record.