

SERVICE SPECIFICATION

Service Specification No.	
Service	Community Pharmacy Take Home Naloxone
Authority Lead	Public Health, Derby City Council
Period	1 st April 2022- 31 st March 2027
Date of Review Supporting/Additional Documentation	n/a

1. Purpose

The Community Pharmacy Take Home Naloxone service provision is available to Pharmacy-based Needle Exchange sites in Derby City.

1.1 Aim

The Community pharmacy Take Home Naloxone service will contribute to Derby's Drug and Alcohol Recovery System. The aims of this system are to:

- Deliver high quality and safe care which is client centred, offering personalised opportunities for those using drugs and/or alcohol to move towards sustained recovery.
- Provide non-judgmental services that are fair and equitable providing good access to all and delivering a range of interventions which are evidence based, cost-effective and are responsive to client need.
- Reduce the level of harm caused to individuals, families and the wider community as a result of drug and alcohol misuse.
- Deliver a recovery focused service which assists clients to attain a good standard of health and wellbeing and achieve a drug free life and/or achieve abstinence from alcohol or controlled drinking.

1.2 Objectives

The objectives of the community pharmacy take home naloxone service are:

- To contribute to the prevention of drug related deaths.
- To increase awareness and the availability of training and supply of Naloxone in Derby City.
- To provide training and supply Naloxone to people at risk of opiate overdose.
- To provide people with a supply of replacement Naloxone following emergency use or date expiry.
- To maximise the benefits of accessing community pharmacies and facilitate behaviour change in people's journey toward recovery, such as general health improvement and signposting to other services including drug treatment.

1.3 Background

In England and Wales in 2019, 4393 deaths relating to drug poisoning were registered. This is the highest number since the data series began in 1993. Around two thirds of all drug poisoning deaths were related to drug misuse and almost half (49.2%) of these involved opiates (ONS, 2020).

Naloxone is the emergency antidote for overdoses caused by heroin and other opiates or opioids (such as methadone, morphine and fentanyl). There is evidence that the distribution of naloxone to drug users, their family members and peers and training on how to administer it can be effective in

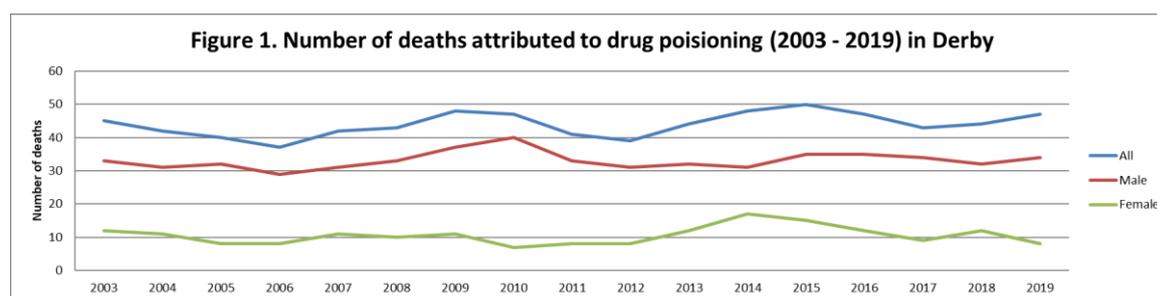
reversing heroin overdoses and save lives.

The legal status of naloxone means that anyone can administer it for the purpose of saving a life. On the first of October 2015 The Human Medicines (Amendment) (No. 3) Regulations 2015 (2015/1503) came into force which allow people working in or for drug treatment services, including Local Authority commissioned Pharmacy Based Needle and Syringe programmes and those delivering opioid substitution treatments through supervised consumption, to supply naloxone for use in an emergency without a prescription or Patient Group Direction. See: [Widening the availability of naloxone - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone)

1.4 Local Context

It is estimated that in Derby there are approximately 2160 opiate and crack users. Around 51% of these people access treatment services at any one time. In 2020 there were approximately 650 people registered to use the city's pharmacy based needle exchanges. Of these, around 66% of people were primary opiate and/or crack injectors.

Providing accessible and engaging services is of primary importance within the city as individuals requiring support from substance misuse services often represent some of the most deprived groups in the city who experience a range of health inequalities and poor health outcomes. Similar to the national trend of increasing drug related deaths Derby has also seen a rise since 2017 (Fig 1. Below)



For several years Derby's Drug and Alcohol Recovery Service based at St Andrew's House has issued naloxone to clients in treatment. This service aims to expand this provision by providing additional outlets in the city for opiate users to obtain naloxone from. This is particularly important for those people not currently engaged in treatment but who do access needle exchange provision as it helps engage drug users into treatment and provides vital opportunities for interventions to take place such as advice about overdose awareness and providing Naloxone.

2. Evidence base

In addition to guidance detailed in the Locally Enhanced Pharmacy Based Needle Exchange service specification. The service will adhere to:

- H.M. Government Guidance: Widening the availability of naloxone: <https://www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone>

Pharmacy's should utilise the following resources:

- Naloxone: Take Home Naloxone in the UK: <https://naloxone.org.uk/>
- Addiction Professionals Educational Resources. Free Learn: Naloxone Saves Lives: <https://www.ap-elearning.org.uk/>

The service is expected to adhere to all such relevant guidance and best practice, including any new

publications in-year, and provide details of compliance where necessary.

3. Service Description

3.1 Service Description

The following elements of service delivery will align to the objectives in Section 1.2.

In delivering this service the Provider will demonstrate compliance with all relevant national standards for service quality and clinical governance including compliance with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

The community pharmacy take home naloxone service will be offered to suitable substance misuse needle exchange clients. The service will:

- Offer a user friendly, non-judgemental, client centred and confidential service.
- Offer Naloxone to anyone who is:
 - Currently using illicit opiates such as heroin
 - Receiving opioid substitution therapy
 - Leaving prison/rehab with a history of drug use
 - Who has previously used opiate drugs (to protect in the event of a relapse)
- Offer Naloxone to a family member, carer, peer or friend of anyone identified above with consent.
- Provide those offered naloxone with brief training in recognising the symptoms of opioid overdose, how to respond appropriately (including CPR and the recovery position) and how to administer naloxone.
- Facilitate access to substance misuse treatment and other health and welfare services as appropriate.
- Adhere to all policies relating to the safeguarding of vulnerable adults and children.

There are two formulations of naloxone suitable for use in the home and non-medical setting, and therefore can be used to supply as part of the take home naloxone programme for use in an emergency:

- Prenoxad[®] solution for Injection - Each kit contains 1 x 2ml pre-filled syringe (Naloxone Hydrochloride 1.0mg/1ml) and 2 x 23G 1.25" needles for intramuscular injection.
- Nyxoid[®] Nasal Spray – Each spray contains 1.8mg naloxone hydrochloride. It is a single use product, the recommended dose being one spray (1.8mg) into the nostril. Each pack contains two individually sealed nasal sprays.

Either can be issued as part of this service specification.

3.2 Service Location and Eligibility

The pharmacy will be located within the city boundary as defined by Derby City Council and will be commissioned to deliver the Locally Enhanced Pharmacy-based Needle Exchange Service.

The service will be available on an open access basis with no requirement for service users to be referred from another agency and will be available across all the opening hours of the designated pharmacy.

4. Service Delivery

4.1 Identification and Assessment

To identify and potentially supply suitable needle exchange clients with take home naloxone. The pharmacy will need to ask some basic information to establish if they are eligible. This will include information about current drug using behaviours and if they have ever been issued naloxone previously from another source. Naloxone can be offered to anyone:

- Currently using illicit opiates such as heroin
- Receiving opioid substitution therapy
- Who has recently left prison/rehab with a history of illicit opiate use
- Who has previously used opiate drugs (to protect in the event of a relapse)
- Who is a family member, carer, peer or friend of anyone identified above - with consent.

Naloxone can be issued to young people under 18 on a case by case basis by an appropriately acting professional who is acting within a suitable clinical governance framework and after careful consideration. Account should be taken of Fraser guidelines and the mental capacity of the young person to understand the issues involved, together with adherence to guidance relating to consent and safeguarding in children and young people.

For specialist advice and guidance on issuing naloxone the dedicate pharmacy only phone line 01332 268460 should be used to contact Derby Drug and Alcohol Recovery Service.

4.2 Training clients, carers and identified others in overdose management

Training on how to recognise opioid overdose, overdose management and the administration of naloxone must be given to suitable clients before naloxone can be supplied. The training will take between 5-10 minutes and should be delivered in a designated consultation area in the pharmacy with sufficient privacy (both auditory and visual) to maintain confidentiality by an appropriately trained member of staff.

The training to patients must cover how to recognise an opioid overdose, how to respond to an opioid overdose and how to issue naloxone (Prenoxad® or Nyxoid®) and the procedure for doing so. Which is to:

- Ensure personal safety first
- Call an ambulance
- Place the casualty in the recovery position, or on their side if breathing
- Place the casualty on their back if not breathing
- Commence chest compressions and rescue breaths if not breathing

If issuing Prenoxad®:

- Inject naloxone into the thigh or upper arm muscle
- Repeat naloxone injections at 2 minute intervals in doses of 0.4mg until breathing commences
- If the patient is still non-responsive and the ambulance services have not arrived Naloxone can continue to be given at 2 minute intervals if there are other kits available to use.
- Wait with the casualty until the ambulance arrives and safely dispose of the naloxone kit to paramedics.

If issuing Nyxoid®:

- Give one dose into the nostril immediately on suspecting an opioid overdose while waiting

for emergency services.

- Repeat chest compressions and rescue breaths until breathing commences
- If the first dose does not have an effect, a second dose should be given after 2–3 minutes in the other nostril.
- If the first dose works well but the patient later worsens a second dose should be given immediately in the other nostril.

Verification of the client’s knowledge and understanding of all aspects of the take-home naloxone training should be confirmed. Only in exceptional circumstances should a supply of naloxone be refused which should be documented.

Training should be completed with a client each time a kit is given out or replaced.

4.3 Issuing Naloxone

Once training in section 4.2 has been completed with the client naloxone can be issued.

This can be either:

- Prenoxad® solution for Injection - Each kit contains 1 x 2ml pre-filled syringe (Naloxone Hydrochloride 1.0mg/1ml) and 2 x 23G 1.25” needles for intramuscular injection.
- Nyxoid® Nasal Spray – Each spray contains 1.8mg naloxone hydrochloride. It is a single use product, the recommended dose being one spray (1.8mg) into the nostril. Each pack contains two individually sealed nasal sprays.

Should there be an identified need for more than one kit, this should be discussed with the Derby Drug and Alcohol Treatment Service based at St Andrew’s House (telephone: 01332 268460) who can provide advice and additional packs directly to the client.

There are no specific storage recommendations for Prenoxad®, Nyxoid® states that it must not be frozen. Once supplied to a client, they should be advised to store the naloxone in a suitable safe place, which is easy to locate but not within reach of children. Once supplied there is no ongoing requirement to monitor room temperature.

Upon issuing naloxone minimum data must be entered into Pharm Outcomes.

4.4 Expired Naloxone and Reissue of Supply

Naloxone has a maximum shelf life of 3 years. When naloxone is supplied this should be explained to the client and the expiry date noted and told to them. Recipients of take home naloxone should be encouraged to return naloxone to the service before the expiry date to collect a further supply. Expired supplies should immediately be placed in sharps collection bins for clinical waste collection and disposal.

If a naloxone kit has been used or partially used clients should be advised that the used syringe and needle of a Prenoxad® kit should be replaced in the cradle in the yellow naloxone kit box when no longer required and the box shut to become a temporary sharps container. Used or partially used kits should be given to the emergency services attending for safe clinical disposal. If no emergency services attend then used kits should be returned to the pharmacy for re-supply and safe disposal.

Before a client is reissued with naloxone they must complete a re-refresh of the training detailed in 4.2. Any reissue of naloxone whether because of expiry or use should be entered into Pharm Outcomes.

4.5 Staff training

The pharmacy must ensure that all pharmacy based staff delivering needle exchange and take home naloxone interventions have relevant knowledge and are appropriately accredited in drug awareness, impacts of substance misuse, blood borne viruses, safeguarding, client centred communications skills, data protection and confidentiality.

Staff supplying naloxone should have been appropriately trained and all staff should Complete the Addiction Professionals Educational Resources FreeLearn: Naloxone Saves Lives online learning package <https://www.ap-elearning.org.uk/>

4.6 Interdependencies: Drug Treatment Services at St Andrews House

A person's engagement with drug treatment and use of prescribed medication is not a barrier to issuing take-home naloxone. Pharmacy based Needle Exchange and the take home naloxone service forms part of Derby's Integrated Drug and Alcohol recovery system. Pharmacies are expected to contact the staff at the Drug and Alcohol Recovery Service if they have any concerns or queries regarding the management of substance using clients. The dedicated 'pharmacy only' telephone number 01332 268460 can be used to make or arrange appointments on behalf of clients or to contact staff at the Drug and Alcohol Recovery Service for specialist support.

4.7 Confidentiality

The take-home naloxone service will be run as a confidential service and will aim to protect the dignity and privacy of the service user. The service must be provided from a designated consultation area in the pharmacy that provides sufficient safety and privacy (both auditory and visual) for delivery of the service.

All records pertaining to needle exchange and the take home naloxone service that contain personal information or information that could lead to the identification of a client will be kept confidential and held in a secure manner. All client documentation that is no longer needed will be disposed of as confidential waste and not disposed of in general waste unless shredded. The pharmacy will ensure it has appropriate mechanisms in place to destroy confidential information in accordance with the Data Protection Act and in accordance with their existing NHSE contract. Pharmacies found not to have a suitable confidential waste removal procedure will have their contract suspended in accordance with the contract terms and conditions.

5. Service Quality

Clinical and Cost Effectiveness

Pharmacies will:

- Satisfactorily comply with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential services and an acceptable system of clinical governance.
- Demonstrate the principle of 'best value' through continuous improvement taking into account a combination of effectiveness (successful outcomes), efficiency (high productivity) and economy (costs).
- Ensure there are designated clinical leadership and accountability, and clear clinical protocols for effective clinical governance.
- Ensure staff are appropriately supported and supervised, including clinical supervision for clinical staff.

Clinical audit

Pharmacies will:

- Ensure the implementation of a clinical audit process to review performance and

provide a framework to enable improvements to be made.

- Allow Derby City Public Health or their nominated representatives' access to their premises in order to facilitate a clinical audit or inspection of the service being provided.

Governance

Pharmacy governance arrangements will include the following:

- Education and training
 - Ensure staff providing the service are suitably qualified and competent and that there are in place appropriate arrangements for maintaining and updating relevant skills and knowledge (see section 4)
- Information management
 - Ensure the service adheres to national and local rules on confidentiality, the Data Protection Act 2018 (DPA 2018) and the UK General Data Protection Regulation (UK GDPR)
 - Ensure that Information sharing protocols are consistent with guidance from the local Caldecott guardian
 - Ensure everyone in the service understands the importance of information rights, and their own responsibility for delivering them
 - have a clear confidentiality/data handling policy, which is understood by all staff handling personal and sensitive information
 - ensure that all data collected is accurate, reliable and able to support performance management arrangements
 - Keep all records relating to the delivery of this contract for 7 years.
 - Regularly review and assess your services data security arrangements.
- Staff management
 - Ensure staff and management working within the service work as an efficient team within a well-supported environment.
 - Ensuring that a process is in place for any member of their business to raise concerns in a confidential and structured way

Care Environment and Amenities

Pharmacies will

- Ensure that all premises and equipment used for the provision of the service are at all times suitable for the delivery of those services and sufficient to meet the reasonable needs of clients or clients.
- The service must be provided from a designated consultation area in the pharmacy that meets, as a minimum, the national standards required for the provision of the Medicines Use Review Service and provides sufficient privacy (both auditory and visual) and safety for delivery of the service.

Risk Management

Pharmacies will

- Ensure there are robust processes, working practices and systematic activities that prevent or reduce the risk of harm to clients
- Ensure there are robust processes in place to support the reporting and review of all untoward incidents at the earliest opportunity. This will include the documentation, investigation and follow up with appropriate action of all untoward incidents (see link to NHS Patient Safety Incident Response Framework below)
- Ensure this learning is disseminated across the organisation and shared with the

commissioners

- Ensure that an effective complaints procedure for clients is in place, in line with the current NHS Complaints Procedure guidance, to deal with any complaints in relation to the provision of the service, which is available for audit
- Ensure that a process is in place for any member of the professional team to raise concerns in a confidential and structured way
- Ensure the service has a nominated lead for safeguarding issues and adheres to the Derby and Derbyshire Safeguarding policies and procedures.
- Ensure that all staff engaged in the provision of the needle exchange service are vaccinated against Hepatitis B; the Council accepts no liability whatsoever howsoever arising in the event that Provider staff contract Hepatitis B as a result of their involvement in the provision of this service.

Client and Carer experience and involvement

Pharmacies will

- Ensure that clients have the opportunity to make informed decisions about their treatment and care in partnership with healthcare professionals. If clients do not have the capacity to make decisions staff should follow the DOH advice on consent and the code of practice that accompanies the Mental Capacity Act.
- Provide opportunities for clients to give feedback to staff/service on their health care or treatment
- Ensure that treatment, care and information provided is evidence based culturally appropriate and is available in a form that is accessible to people who have additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.
- Reviewing the findings of any client satisfaction surveys and implementing any recommendations as a result
- Ensuring that an effective complaints procedure for the pharmacies is in place, to deal with any complaints in relation to the provision of the goods

Derby City Council reserves the right to

- Utilise 'mystery shoppers' as part of their quality assurance framework.
- Consult with service users regarding satisfaction with the service provided on a regular basis and the pharmacy will permit Public Health or their nominated representatives on to their site in order to consult with clients accessing the service.
- Undertake clinical audits of the Take Home Naloxone Service within the pharmacy using nominated 3rd party clinical representatives.

Accessible and Responsive Care

Pharmacies will

- Ensure the service offers equitable access to treatment and care within agreed timescales
- Ensure the service takes account of race, disability, gender, sexual orientation in the planning and delivery of treatment and care

Safeguarding

The pharmacy must ensure that they adhere to applicable local standards including but not exclusively:

- Derby and Derbyshire Safeguarding Children Procedures
https://derbyshirescbs.proceduresonline.com/register_updates.html
- Derby and Derbyshire Adults Protection Policy and Procedures.
<https://www.derbysab.org.uk/media/derby-sab/content-assets/documents/Joint-Derby-and-Derbyshire-SAB-Policy--Procedures-December-2019.pdf>

The pharmacy must ensure that policies and procedures relating to safeguarding are adhered to and that staff have undertaken safeguarding training appropriate for their professional role. All staff operating the service will have an up to date Disclosure and Barring Service check.

Serious Incident Reporting

All serious incidents will be reported in accordance with the NHS Patient Safety Incident Response Framework

<https://www.england.nhs.uk/patient-safety/serious-incident-framework/>

6. Contract management

6.1 Claims

Payment will be made per site in accordance with the number of naloxone kits issued each month. A fee of £15.00 will be paid for each supply of naloxone made in accordance with this service specification.

Invoices will be automatically generated by PharmOutcomes at 12.01am on 3rd of each month. Invoices directly relate to the individual client record kept on PharmOutcomes. All claims are to be submitted via PharmOutcomes **within 1 month** of the transaction taking place. Derby City Council will not pay any claims that are submitted beyond the 1 month allowable timescale.

6.2 Stock

Stock holding on site can be kept to a minimum due to the rapid order and delivery system that the Derby City Council designated needle exchange and naloxone supplier has in place. All stock ordered remains the property of Derby City Council, who reserves the right to carry out an audit of any stocks of naloxone goods held by the pharmacy - in order to reduce the likelihood of loss or waste. Derby City Council will use PharmOutcomes to monitor pharmacy activity, financial claims and to reconcile the supply of goods on a site by site basis - against the number of naloxone kits issued. In the event of any loss or damage caused to stock on the pharmacy site the pharmacy will report this as soon as practicable to Derby City Council Public Health.

The pharmacy can only hold a maximum of 6 Prenoxad[®] kits and 4 Nyxoid[®] kits in stock unless it has been agreed otherwise with the Commissioner. Naloxone kits purchased under this agreement should be kept segregated and only used for the provision of this service.

Derby City Council will use PharmOutcomes to monitor pharmacy activity, financial claims and to reconcile the supply of stock on a site by site basis - against the number of naloxone packs issued. In the event of any loss or damage caused to stock on the pharmacy site the pharmacy will report this as soon as practicable to Derby City Council Public Health.

7. Performance

The pharmacy is expected to comply with any reasonable performance management arrangements requested by Derby City Council.

Performance will be monitored using the measures identified in the table below. If there are any concerns relating to the delivery of this service discussions will take place directly between the commissioner and pharmacy. This may take the form of site visits or requests for the pharmacist/superintendent to attend formal meetings. Findings from audits or patient surveys will be managed in the same way.

Outcome	Output	Measure	Frequency
Greater awareness and availability of naloxone.	Number of individuals trained and supplied with Naloxone kits.	PharmOutcomes data	Monthly
Greater engagement and treatment of traditionally underserved and hard to reach communities in specialist drug treatment services	Number of individuals referred to the Derby Drug and Alcohol Recovery Service	PharmOutcomes data	Monthly
Evaluation/Quality service delivery	On site audits.	Commissioner report	As required
Clients satisfaction with pharmacy providing the service	Customer satisfaction survey (carried out by 3 rd party on behalf of DCC)	100%	Annually

8. Sub-contractors

No sub-contractors will provide any element of this contract unless agreed in writing by the Commissioner prior to the sub-contractor starting work.