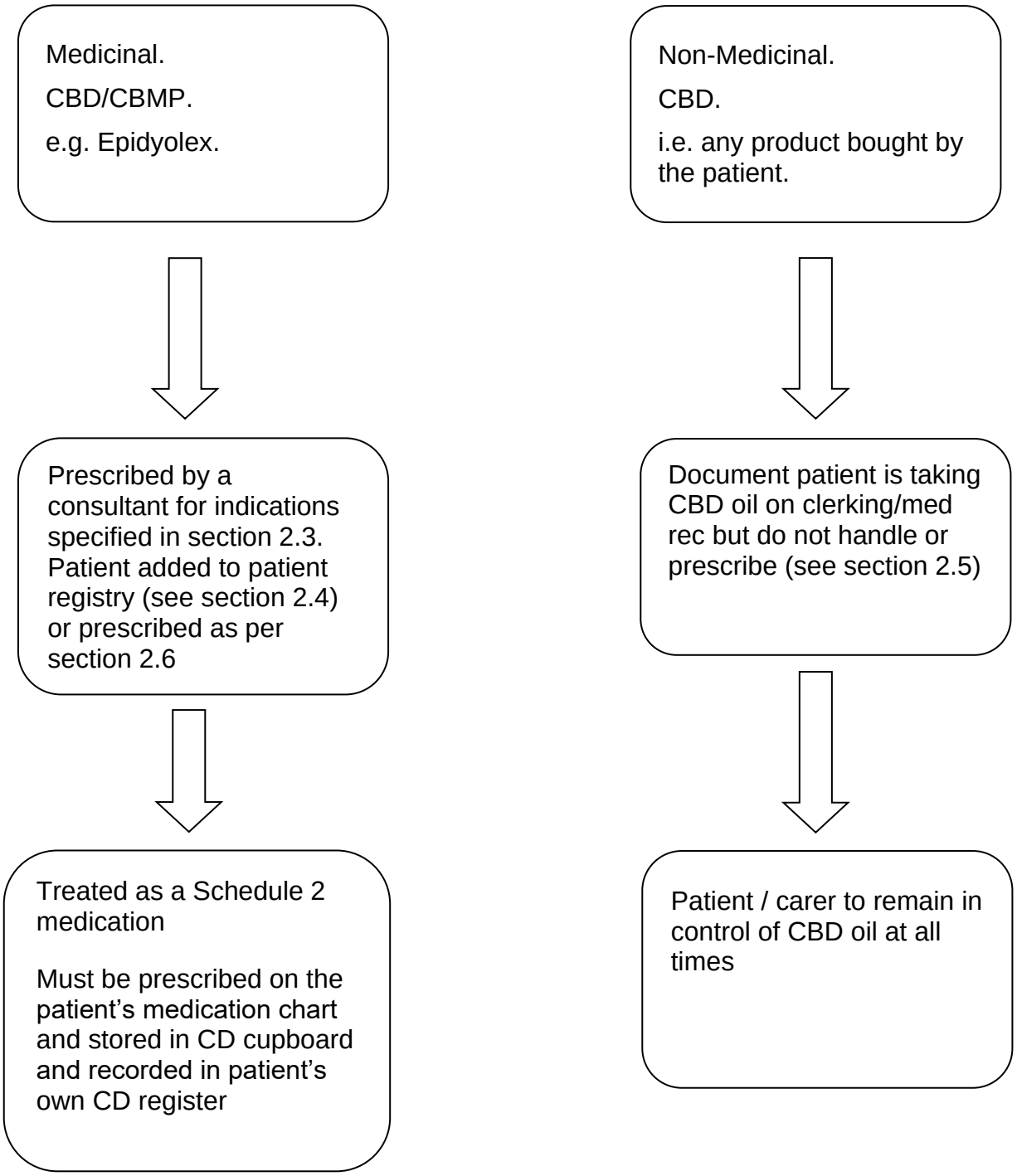
Royal Cornwall Hospitals
NHS Trust

Use of Cannabidiol (CBD) and other Cannabis-Based Medical Products (CBMPs) Clinical Guideline

V4.0

April 2025

Summary


Medicinal.
CBD/CBMP.
e.g. Epidyolex.
Non-Medicinal.
CBD.
i.e. any product bought by the patient.
Prescribed by a consultant for indications specified in section 2.3. Patient added to patient registry (see section 2.4) or prescribed as per section 2.6
Document patient is taking CBD oil on clerking/med rec but do not handle or prescribe (see section 2.5)
Treated as a Schedule 2 medication
Must be prescribed on the patient's medication chart and stored in CD cupboard and recorded in patient's own CD register
Patient / carer to remain in control of CBD oil at all times

1. Aim/Purpose of this Guideline

1.1. This guideline covers the use of CBD oil and CBMP in all inpatient areas within RCHT.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. Introduction

2.1.1. CBD, a constituent of cannabis, is widely available to purchase online and from health food shops. These are marketed and sold as dietary supplements but are commonly bought by patients for use as a medicine for a variety of ailments including anxiety, muscle spasticity and epilepsy.

2.1.2. CBMP outside of NICE guideline recommendations can be prescribed by private specialist clinics. This has made CBMP accessible for conditions with limited evidence of benefit and where it's not recommended by NICE.

2.2. Background

2.2.1. Cannabis is controlled under the misuse of drugs legislation. CBD as an isolated substance would not be controlled under the Misuse of Drugs Act. However, if a CBD 'product' contained any controlled cannabinoids, unintentionally or otherwise (e.g. THC or CBD-V), then it is highly likely that the product would be controlled. In practice it is very difficult to isolate pure CBD, and due to the nature of the products available the contents are often not fully disclosed. As a result of this it has to be assumed that CBD containing products would be controlled under the MDA 1971/MDR 2001 as a result of other cannabinoid content.

2.2.2. An amendment to the Misuse of Drugs Regulations 2001 came into force 1st November 2018, which allows the use of cannabis-based products, such as CBD oil, for medicinal use. This amendment states that products will only fall under the definition of “cannabis-based products for medicinal use” if it fulfils the three limbs of the definition of ‘cannabis-based product for medicinal use in humans’, whereby it will be treated as a Schedule 2 drug under the 2001 regulations. The three limbs are that the preparation or product (other than Sativex or those with a home office exemption):

1. Is or contains cannabis, cannabis resin, cannabinol or cannabinol derivative (e.g. THC).

2. Is produced for medicinal use in humans.

3. Is a medicinal product, or a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.

2.2.3. Cannabis based products for medicinal use may be legally accessed in 3 ways, as stated in the November 2018 amendment:

“A person shall not order (whether by issuing a prescription or otherwise) a cannabis-based product for medicinal use in humans for administration to himself or herself or to another unless that product is:

1. A special medicinal product (e.g. unlicensed medicines) that is for use in accordance with a prescription or direction of a specialist medical practitioner.

2. An investigational medicinal product without marketing authorisation that is for use in a clinical trial or,

3. A medicinal product with a marketing authorisation.”

2.2.4. Initial prescribing is currently restricted to doctors on the Specialist General Medical Council Register. NICE guidance allows for “subsequent prescriptions of cannabis-based medicinal products to be issued by another prescriber as part of a shared care agreement under the direction of the initiating specialist prescriber, if:

- Shared care is appropriate and in the person's best interest.

- The person's clinical condition is stable.

- The other prescriber is confident to make a fully informed prescribing decision about cannabis-based medicinal products.”

2.2.5. In cases where a shared care agreement is deemed appropriate, the agreement must include:

- The responsibilities of all parties [the initiating specialist prescriber, the other prescriber(s), the patient, family and/or carers].

- The nature and frequency of monitoring and how this will be recorded.
- When treatment might be stopped, for example, if it is not effective.
- How suspected or known adverse reactions will be managed.
- How communication will be managed between the initiating specialist prescriber, the other prescriber, the patient, family and/or carers.
- How the treatment will be funded. Epidyolex is a high cost drug and consideration on how this will be funded is essential.
- How care will be maintained when the patient, initiating specialist prescriber or other prescriber moves location (including transition to adult services).

2.3. What does this mean in practice?

2.3.1. In practice this means that only consultants within the Trust are able to initiate products which have been produced for medicinal use and have been approved for importation by the MHRA (Medicines and Healthcare products Regulatory Agency) or are licensed as medicines for use in the UK. It is recommended that prior to use approval will be obtained from the medical director or the chair of the Medicines Practice Committee (MPC) on a named patient basis. This is also true for those patients where a shared care agreement is being considered. NHS England have also stipulated that the only approved indications are:

- Children and adults with rare forms of epilepsy.
- Adults with nausea and vomiting caused by chemotherapy.

2.3.2. All other CBD products e.g. herbal remedies and other products that are not prescribed for that patient must continue to be treated as controlled substances under the misuse of drugs legislation.

2.3.3. Epidyolex 100mg/mL oral solution is a product recently licensed in the UK for the treatment or rare forms of epilepsy (Dravet's syndrome and Lennox-Gastaut) in combination with clobazam. It is likely that this will be the preferred product to be used. Epidyolex is a Schedule 5 controlled drug but will be treated as a schedule 2 within RCHT requiring storage in the controlled drug cupboard.

2.3.4. NICE released guidance on the use of Cannabis-based medicinal products in November 2019 (NG144). This guidance covers 4 areas:

- Chronic pain.
  - Cannabis products not recommended.
- Intractable Chemotherapy Induced Vomiting (CINV).

- Consider use of nabilone.

- Severe treatment resistant epilepsy.
  - Cannabidiol to be used in conjunction with clobazam in patients with Lennox-Gastaut and Dravet Syndromes.

- Spasticity in Multiple Sclerosis (MS).

2.3.5. Sativex would initially be prescribed by a Consultant (e.g. Neurology) before consideration for sharing care with primary care.

2.3.6. Further information can be found in the NICE guidance "Cannabis-based medicinal products (NG144)" available at www.nice.org.uk . Use of cannabis based medicinal products outside of NICE guidance must be approved by the medical director before use, unless it was initiated prior to the guidance being releases (i.e. prior to November 2019).

2.4. Patient registration

2.4.1. In the UK it is a national requirement that all patients receiving prescribed cannabis-containing products are added to the patient registry

2.4.2. All prescribers issuing prescriptions for Cannabis Based Products for Medicinal Use (CBMPs) must make relevant register entries and keep them up to date as soon as possible after prescriptions are issued.

2.4.3. Further information on obtaining access to the registry can be found on the NHS England website Cannabis based products for medicinal use

2.5. Inpatient supplies of medicinal cannabidiol

Wherever possible patient's own supplies should be used, and resupply from the patient's tertiary centre or usual prescriber should be requested before supplies run out. Only in exceptional circumstances, where the patient's treatment will be otherwise interrupted, supply may be provided to the ward.

2.6. Use of CBMP for indications not recommended by NICE and issued by private specialist clinics

2.6.1 The hospital permits the use of CBMP for non-NICE indications where clinically appropriate as prescribed by a GMC-registered specialist doctor. The patient must present the following evidence:

2.6.1.1 Copy of the issuing private clinical letter or prescription, dated within 90 days of patient's admission to hospital.

2.6.1.2 Medication in its original container with a legible pharmacy label that meets the medicines labelling regulations including the patient's name.

2.6.1.3 The pharmacy dispensing the medication must be contacted to confirm that they have dispensed the medication to the patient in the last 90 days.

2.6.2 Prescribing for inpatients

2.6.2.1 CBMP must be prescribed exactly as per private prescription presented and corroborated by medicines reconciliation.

2.6.2.2 Changes must not be made to the prescription without a documented direct review of the patient by the private medical cannabis clinic.

2.6.3 Administration routes and patient management.

2.6.3.1 Oral formulations: Include oils and pastilles, taken sublingually or ingested.

2.6.3.2 Vaporisation: Includes dry herb vaporisers and vape cartridges. Vaping inside RCHT buildings is not permitted in line with fire safety policies. Vaping medical cannabis is only allowed outside the building.

2.6.3.3 CBMPs are self-administered by patient or caregiver, with supervision from nursing staff if needed.

2.6.3.4 Upon admission, any CBMP brought by the patient must be reviewed and verified by pharmacy staff.

Smoking cannabis remains illegal, even when the patient has a prescription for cannabis flower intended for use with a vaporiser. Patients are legally entitled to use and possess these medicines as prescribed, and they must follow the prescribed methods of use. Smoking is prohibited under all circumstances.

2.6.4 Storage and record keeping

2.6.4.1 CBMP must be securely stored in controlled drug cabinet in line with controlled drug policy for Schedule 2 medications.

2.6.4.2 CBMP must be recorded in patient's own section in Controlled drug register. For oral formulation such as pastilles, enter the number of pastilles in pack. For other formulations such as oils, vapes, enter the number of containers/devices brought in by patient in hospital.

2.6.5 Patient discharge

2.6.5.1 Patients must take all the remaining CBMP with them on discharge.

2.6.5.2 Re-supplies during admission or on discharge WILL NOT be made by hospital pharmacy even if the patient runs out of supply.

2.6.5.3 Discharge summaries should include a record of CBMP use, with details shared with the patient's GP.

2.7 Use of non-medicinal Cannabidiol within RCHT

2.7.1 Non-medicinal Cannabidiol for the purposes of this guidance is defined as any cannabidiol product that is being used outside of the November 2018 amendment to the Misuse of Drugs Regulations 2001 i.e. any cannabidiol which has not been prescribed by a consultant and dispensed by a registered pharmacy. The table below can be used to help choose the correct action to take:

Patient brings in	What to do
Legitimately prescribed licensed product (e.g. Sativex, Epidyolex) used for licensed indication (i.e. has dispensing label attached).	Treat as a patient's own controlled drug - record in Patient's own register and store in CD cupboard.
Legitimately prescribed unlicensed product or licensed product used for an unlicensed indication (off-label).	As above but pro-actively seek assurance that prescribing is appropriate. Raise any concerns with the CD accountable officer.
Food supplement product obtained from health food store or online.	Advise patient to take medication home. If patient unwilling to do this follow advice below.
Entirely illicit product for smoking etc (no suspicion patient is supplying to others).	Take possession for purpose of destruction. Do not give it back to the patient. Signpost to support as appropriate. See also section 4.14 of the Ward, Theatre and Department, Controlled Drugs, Standard Operating Procedure on the RCHT document library for further information.
Entirely illicit product for smoking etc (any suspicion patient is supplying to others).	Take possession as evidence, report as a crime and notify CD accountable officer See also section 4.14 of the Ward, Theatre and Department, Controlled Drugs, Standard Operating Procedure on the RCHT document library for further information.

2.7.2 Actions for prescribers

- Document the fact that the patient is taking CBD oil on the admission paperwork.
- Be aware that CBD oil has potential drug interactions.
- Do NOT prescribe CBD oil.

- The patient (or carer) should be informed that if the patient (or carer) wishes to continue to take CBD oil, they must do so themselves as staff will not legally be able to administer it. In order for this to occur, the patient must be assessed under the self-administration of medicines policy, and only those patients (or parents/carers for paediatric patients) assessed as suitable to self-administer will be able to take their own CBD.

- Do not handle or accept the CBD oil, and then return it to the patient, as doing so could be construed as 'supply of an illegal substance'.

- Include the fact the patient takes CBD oil in the discharge summary, but do not prescribe it in the medicines section.

2.7.3 Actions for pharmacists

- Include CBD oil in the medicines reconciliation.

- Assess the patient (or parent/carer for paediatric patients) for suitability to self-administer under the self-administration of medicines policy.

- Ensure that CBD oil is not prescribed or included in the medicines section of the discharge summary. Where it is prescribed the prescribing doctor should be notified and the CBD oil removed from the chart by the prescriber.

- Add a pharmaceutical care plan note to alert all staff involved in the patient's pharmaceutical care that the patient is taking CBD oil to allow for interactions to be checked.

2.7.4 Actions for nurses

- Assess the patient (or parent/carer for paediatric patients) for suitability to self-administer under the self-administration of medicines policy.

- Do not administer CBD oil to the patient.

- Do not handle a patient's CBD oil unless they authorise you to destroy it on their behalf. If this occurs record this in the patient's own CD register and notify the ward pharmacist to arrange collection (see section 13).

2.7.5 Actions for patients

Patients (carers) will need to keep the CBD oil in their possession in a locked medicines cabinet, and remain responsible for it throughout their stay.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Storage errors.
Lead	Accountable officer or deputy.
Tool	Review of DATIX and CD variance reports.
Frequency	Annually
Reporting arrangements	Reports will be reviewed by Medication Practice Committee (MPC). Reviews will be minuted at this meeting and any actions logged.
Acting on recommendations and Lead(s)	Accountable office or deputy.
Change in practice and lessons to be shared	Required changes in practice will be identified and actioned within 3 months. A lead member from MPC will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

4. Equality and Diversity

4.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

4.2 Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Use of Cannabidiol (CBD) and Cannabis-Based Medicinal Products (CBMPs) Clinical Guideline V4.0
This document replaces (exact title of previous version):	Use of Cannabidiol (CBD) Products Clinical Guideline V3.0
Date Issued/Approved:	31 March 2025
Date Valid From:	April 2025
Date Valid To:	April 2028
Directorate / Department responsible (author/owner):	Sabrina Tierney, Clinical Pharmacist. Helen McClay, Deputy Chief Pharmacist.
Contact details:	01872 252590
Brief summary of contents:	This guidance covers the use of CBD oil in all inpatient areas within RCHT.
Suggested Keywords:	CBD, cannabidiol, CBMP, cannabis, cannabis-based medicinal products.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Medication Practice Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None required
Related Documents:	Ward, Theatre and Department Controlled Drugs Standard Operating Procedure.
Training Need Identified?	No

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
14/11/2018	V1.0	Initial Issue	Sabrina Tierney, Clinical Pharmacist
02/04/2020	V2.0	Update in view of NICE guidance and licensing of Epidyolex.	Sabrina Tierney, Clinical Pharmacist
01/10/2020	V2.1	• Updated w.r.t Epidyolex CD schedule. • Information on inpatient supply added. Additional information added regarding treatment of patient's own medication on admission.	Sabrina Tierney, Clinical Pharmacist
01/01/2021	V2.2	Updated w.r.t Sativex.	Michael Wilcock, Prescribing Support Pharmacist, Sabrina Tierney, Clinical pharmacist
01/12/2022	V3.0	Updated w.r.t patient registration. Placed on latest accessible Trust template.	Sabrina Tierney, Clinical Pharmacist
20/03/2025	V4.0	Section 2.6 update to include use of CBMP for indications not recommended by NICE and issued by private specialist clinics. Title updated to include CBMP	Helen McClay, Deputy Chief Pharmacist

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Use of Cannabidiol (CBD) and Cannabis-Based Medicinal Products (CBMPs) Clinical Guideline V4.0
Directorate and service area:	Pharmacy, Clinical Support
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Sabrina Tierney, Clinical Pharmacist
Contact details:	01872 252590

Information Category	Detailed Information
1. **Policy Aim - Who is the Policy aimed at?** (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	This guideline covers the use of CBD oil and CBMP in all inpatient areas within RCHT, providing information on safe storage and who can prescribe.
2. **Policy Objectives**	To provide information on safe storage and use of CBD oil and CBMP within RCHT.
3. **Policy Intended Outcomes**	Safe and legal use of CBD oil and CBMP.
4. **How will you measure each outcome?**	DATIX, CD variance reports.
5. **Who is intended to benefit from the policy?**	All staff involved with medicine prescribing and storage.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Child Health Guidelines Committee. Medication Practice Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Sabrina Tierney, Clinical Pharmacist

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis