

**Patient Group Direction For The Supply Of Emtricitabine
200mg/Tenofovir Disoproxil 245mg Tablets By Sexual Health Nurses
Working Within NHS Grampian, NHS Highland and NHS Shetland For
Pre Exposure Prophylaxis (PrEP) To Individuals At Risk Of HIV
Infection**

Lead Author: Consultant in Sexual Health and HIV	Consultation Group: See relevant page in the PGD	Approver: Medicines Guidelines and Policies Group Authorisation: NHS Grampian
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Signature: 		Signature: 
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NoS Identifier: NoS/PGD/PrEP/ MGPG1200	Review Date: November 2023 Expiry Date: November 2024	Date Approved: November 2021
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NHS Grampian, NHS Highland and NHS Shetland have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2.1 (Amended January 2024)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NoS/PGD/PrEP/MGPG1018	
Date of change	Summary of Changes	Section heading
August 2021	2 yearly review with NHS Tayside removed from PGD.	
August 2021	Additional information added.	Route/Method of administration
November 2021	Abbreviation MSM changed to GBMSM as per medic signatory request.	Throughout
January 2024	Added NHS Shetland to PGD and NoS executive sign off.	

NoS Identifier: NoS/PGD/PrEP/MGPG1200
Keyword(s): PGD Patient Group Direction HIV Pre-exposure prophylaxis PrEP Emtricitabine Tenofovir Disoproxil

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document: Drafted: August 2021
 Completed: September 2021
 Approved: November 2021 (published – November 2021)
 Amended and January 2024
 reauthorised:


Organisational Authorisations

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


PGD Developed/Reviewed by;

<p>Medical practitioner</p>	<p>Name: Dr Steve Baguley Health Board: NHSG Title: Consultant in Sexual Health and HIV, NHSG Contact email: steve.baguley2@nhs.scot Signature:  Date: 24/11/2021</p>
<p>Senior Representative of the professional group who will provide care under the direction (if different from below)</p>	<p>Name: Julia Penn Health Board: NHSG Title: Sexual Health Nurse Team Leader, NHSG Contact email: Julia.penn@nhs.scot Signature:  Date: 17/11/2021</p>
<p>Lead author</p>	<p>Name: Dr Daniela Brawley Health Board: NHSG Title : Consultant in Sexual Health and HIV, NHSG Contact email: daniela.brawley@nhs.scot Signature:  Date: 16/11/2021</p>
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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		31/01/2024

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		31/01/2024

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:

Title:

Dr Daniela Brawley
Alison Jane Smith
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Lead Author: Consultant in Sexual Health and HIV NHSG
Pharmacist: Medicines Management Pharmacist NHSG
Medical Practitioner: Consultant Sexual Health and HIV NHSG
Senior Representative: Sexual Health Nurse Team Leader NHSG
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Service Manager/Lead Nurse Sexual Health NHSH

Patient Group Direction For The Supply Of Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets By Sexual Health Nurses Working Within NHS Grampian, NHS Highland and NHS Shetland For Pre Exposure Prophylaxis (PrEP) To Individuals At Risk Of HIV Infection

Clinical indication to which this PGD applies

<p>Definition of situation/Condition</p>	<p>This Patient Group Direction (PGD) will authorise senior sexual health nurses to supply Emtricitabine 200mg/tenofovir disoproxil 245mg tablets to individuals for Pre Exposure Prophylaxis (PrEP) in combination with advice on safer sex practices to reduce the risk of sexually acquired HIV infection in adults at high risk.</p> <p>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<p>The participant population for this PGD will be individuals attending Sexual Health Service clinics who are eligible for PrEP according to the following Scottish national eligibility criteria:</p> <p>Universal criteria:</p> <ul style="list-style-type: none"> • Aged 16 or over • Tested HIV negative • Able to attend the clinic for regular 3 monthly review including for monitoring, sexual health care and support, and to collect prescriptions • Willing to stop NHS-funded PrEP if the eligibility criteria no longer apply • Resident in Scotland <p>Plus one or more of the following eligibility criteria:</p> <ul style="list-style-type: none"> • Current sexual partners, irrespective of gender, of people who are HIV positive and with a detectable viral load • Gay, bisexual and other men who have sex with men (GBMSM)* and transgender women with a documented bacterial rectal STI in the last 12 months • GBMSM* and transgender women reporting condomless penetrative anal sex with two or more partners in the last 12 months and likely to do so again in the next three months • Individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.

	<p>*The term GBMSM used here includes transgender men who have male sexual partners.</p> <p>Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual Board consent policy.</p>
<p>Exclusion criteria</p>	<p>Individuals are excluded from receiving a supply of PrEP if they:</p> <ul style="list-style-type: none"> • Do not meet all of the national eligibility criteria and at least one of the additional eligibility criteria • Are under 16 years of age • Are 16 years of age and over and assessed as lacking capacity to consent • Have a known hypersensitivity or allergy to emtricitabine or tenofovir disoproxil or to any component of the product - see current Summary of Product Characteristics (SmPC) for active ingredients and excipients • Have an acute viral illness at enrolment or within the last month that could represent HIV seroconversion • Are known to be HIV positive • Have renal failure where eGFR less than 60ml/minute • Have known Hepatitis B infection • Have proteinuria ++ or +++ on urinalysis • Have osteoporosis • Have known liver failure or hepatic disease • Are immunocompromised individuals • Are pregnant or breastfeeding • Have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • Are concomitantly taking any of the following drugs: <ul style="list-style-type: none"> ○ Emtricitabine ○ Tenofovir (all salts) ○ Adefovir dipivoxil ○ Lamivudine and other cytidine analogues ○ Didanosine ○ Cidofovir and other medicines that compete for active tubular secretion ○ Medicines that reduce renal function* • Where there is no valid consent. <p>*Consult the latest edition of the BNF for further information.</p> <p>Discuss with a Consultant in Sexual Health/Genitourinary Medicine (GUM) if any of the exclusion criteria are met.</p>

<p>Precautions and special warnings</p>	<ul style="list-style-type: none"> • Adults with renal impairment: individuals with eGFR 60-90mL/minute - monitor renal function more frequently in line with BHIVA / BASHH guidelines • If proteinuria + on urinalysis at baseline, send a urine sample for urine protein/creatinine ratio and blood for eGFR and discuss the results with an Independent Prescriber but proceed with supply pending result • Individuals with lower bone mineral density (BMD) (osteomalacia or osteopenia) or risk factors for bone loss should be counselled to reduce factors associated with low BMD in line with BHIVA/BASHH guidelines • If treatment is interrupted, discontinued or poor compliance is reported this should be discussed with an Independent Prescriber where the decision may be taken to start a new episode of care under the PGD • Discuss with an Independent Prescriber regarding conditions/medicines/side effects of which the health care professional is unsure • In the event of dose modifications, interruptions, overdoses and treatment discontinuations, an Independent Prescriber should be notified and the patient closely observed and managed according to the current local guidelines.
<p>Action if excluded or individual declines treatment</p>	<ul style="list-style-type: none"> • If patient declines treatment, ensure individual is aware of the reasons this medication has been offered and the potential consequences of not receiving it. Record reason for declining in the individual clinical record • If individual tests HIV positive at enrolment manage as per local pathway (refer to local HIV services) • If recent HIV seroconversion is suspected (<1 month) defer initiation until outside window period for testing and repeat HIV test(s) <ul style="list-style-type: none"> ○ If then tests HIV negative can proceed under PGD ○ If then tests positive refer to HIV services as per local pathway • If currently showing symptoms of HIV seroconversion - refer to the appropriate independent prescriber • If an HIV test is reactive/positive whilst taking PrEP, perform confirmatory serology with a combined antigen/antibody test, HIV viral load and resistance testing and consider therapeutic drug monitoring (TDM). Refer to HIV service as per local pathway • If eGFR less than 60mL/minute - refer to an Independent Prescriber for further investigation and consideration of PrEP • Individuals with Hepatitis B should be managed by a hepatologist and therefore are excluded from being treated under this PGD

	<ul style="list-style-type: none"> • If excluded, explain the reasons for exclusion to the individual and document in the individual's clinical record • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options • Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
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Description of treatment available under the PGD

Name form and strength of medicine	Emtricitabine 200mg/tenofovir disoproxil 245mg film-coated tablets.
Legal status	<p>Emtricitabine 200mg/tenofovir disoproxil 245mg tablets are a Prescription-only Medicine (POM).</p> <p>In accordance with the MHRA all medicines supplied under a PGD must either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply.</p> <p>This PGD includes off label use in the following conditions:</p> <ul style="list-style-type: none"> • Event based dosing (EBD) included in this PGD is outside the product licence but accepted and supported practice as per BASHH/BHIVA PrEP Guidelines 2018, English Impact Trial Protocol and the IPERGAY study.
Dosage/Maximum total dose	<p>Risk assessment and discussion between participant and practitioner will determine the regimen to be followed.</p> <p>For GBMSM</p> <p>Option 1 - Daily Regimen: Day 1: Take two tablets 2-24 hours prior to anticipated sexual intercourse. Continue with one tablet per day thereafter.</p> <p>When discontinuing, PrEP should be continued for 48 hours after the last condomless sex has occurred.</p> <p>Option 2 - On-demand (OD) or Event Based Dosing (EBD) Regimen: Take two tablets 2-24 hours before sexual intercourse and 1 tablet at 24 and 48 hours after the initial dose.</p> <p>If further sexual intercourse continue with a daily tablet on each day sex happens.</p>

	<p>When discontinuing, PrEP should be continued for 48 hours after the last condomless sex has occurred.</p> <p>NOTE: EBD is not recommended for heterosexual men, heterosexual women, transgender women and men having frontal/vaginal sex as this regimen has not been evaluated in clinical trials in these groups.</p> <p>Heterosexual, cisgender men and women and transgender men and women having frontal/vaginal sex</p> <p>Daily Regimen: 1 tablet once daily for a minimum of 7 days prior to first sexual intercourse and for at least 7 days after last sexual intercourse.</p> <p>This requires 7 days of dosing to be effective before sex can occur and for 7 days after last sex has occurred.</p> <p>NOTE: Ensure the individual has additional clear written information provided on the appropriate regimen.</p>
<p>Frequency of dose/Duration of treatment</p>	<p>Participants may stop PrEP at any time for the following reasons:</p> <ul style="list-style-type: none"> • Change in the participant’s sexual behaviour meaning indications for PrEP are no longer met • They choose to stop taking the medication • Develop side effects/complications • Start an interacting medication.
<p>Maximum or minimum treatment period</p>	<p>No maximum or minimum period.</p>
<p>Route/Method of administration</p>	<p>Oral. Tablets may be dispersed in a small amount of water if swallowing difficulty.</p>
<p>Quantity to be supplied</p>	<p>Appropriately labelled, complete packs of 30 tablets up to a maximum of 6 packs to be supplied.</p> <p>It is recommended that 3 months be supplied when initiating or re-starting Prep A subsequent 6 month supply can be given if arrangements are made for 3 monthly STI and HIV tests (either face-to-face or online).</p> <p>NOTE: Quantity to supply will be defined by eligibility, expected usage and local commissioning framework.</p>
<p>Storage requirements</p>	<p>Do not store above 30°C. Store in the original package in order to protect from moisture.</p>

<p>Follow-up (if applicable)</p>	<p>The following monitoring is required during ongoing treatment:</p> <p>Three monthly the following must be performed:</p> <ul style="list-style-type: none"> • Assess eligibility and exclusion from PGD • A 4th generation HIV test • STI screen for chlamydia, gonorrhoea and syphilis • Hepatitis C testing according to established practice supported by clinical evidence • Completion of STISS PrEP coding. <p>Every 3-12 months according to local protocol;</p> <ul style="list-style-type: none"> • Serum creatinine and potassium as part of renal function testing/eGFR and urinalysis. Urinary protein/creatinine ratio should be sent if raised protein on urinalysis or other risk factors. <p>NOTE: Regular review of the prescribing and dispensing of PrEP should be undertaken in conjunction with the above three monthly monitoring.</p>
<p>Advice (Verbal)</p>	<ul style="list-style-type: none"> • Advise individual what to expect and what to do for minor and major reactions. • Ensure individual is counselled as to which regimen is to be followed and that they also have clear written information provided on the appropriate regimen and the non-applicable regimen has been crossed out on the supplied product label. • If needed, the tablet(s) can be dispersed in approximately 100mL of water, orange juice or grape juice and the full amount of liquid taken immediately. • There are no requirements for PrEP to be taken with/after food. • Advise individual that if they vomit within 1 hour of taking a dose a single repeat dose should be taken. • Advise to note date a new medicines container is opened and to either use or discard medicines in line with expiry information on the container. • Advise if individual is concerned about any side effects they experience they should contact their clinic as soon as possible. • Advise individuals to report any new medicines to prescriber/pharmacist to check for interactions with this drug. <p>Clinical:</p> <ul style="list-style-type: none"> • Advise on condom use and risk of other STIs. PrEP provision should include condom provision and behavioural support. • Advise that PrEP is not a contraceptive.

	<ul style="list-style-type: none"> • Advise PrEP is not 100% effective and on the importance of regular 3 monthly HIV/STI testing in-clinic or online. • Information should be provided to all patients on: <ul style="list-style-type: none"> ○ PrEP medication dose and schedule ○ Lead-in time to protection ○ Relationship of adherence to PrEP efficacy ○ Risks of HIV infection and antiretroviral resistance from suboptimal adherence ○ Symptoms of HIV seroconversion that require assessment <p>If serious adverse effects occur, the individual should be advised to contact NHS24 if prescribing service is not available/out of hours.</p>
<p>Advice (Written)</p>	<p>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p> <p>Adherence and dosing information including patient information leaflet or locally agreed alternative to support use and understanding of use. Information is available through:</p> <ul style="list-style-type: none"> • What is PrEP/Terrence Higgins Trust • PrEPster • i-base and i-base UK Guide to PrEP
<p>Identifying and managing possible adverse reactions</p>	<p>The following side effects are reported with emtricitabine/tenofovir disoproxil:</p> <ul style="list-style-type: none"> • diarrhoea, vomiting, nausea • dizziness, headache • rash • feeling weak • pain, stomach pain • difficulty sleeping, abnormal dreams • problems with digestion resulting in discomfort after meals, feeling bloated, flatulence • rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches • other allergic reactions, such as wheezing, swelling or feeling light-headed • swelling of the face, lips, tongue or throat. <p>This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.</p>

	<p>BNF: BNF British National Formulary - NICE</p> <p>SmPC/PIL/Risk Minimisation Material: Home - electronic medicines compendium (emc) MHRA Products Home RMM Directory - (emc)</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the medicine is to be supplied:</p> <ul style="list-style-type: none"> • Appropriate storage facilities • An acceptable level of privacy to respect individual’s right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

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

<p>Professional qualifications</p>	<p>Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).</p>
<p>Specialist competencies</p>	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individual’s capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD.
<p>Ongoing training and competency</p>	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken PGD training as required/set out by NHSG

	<ul style="list-style-type: none"> • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ SmPC for the medicine(s) to be supplied in accordance with this PGD ○ Relevant local protocol relating to PrEP and the monitoring of individuals taking the medicine. Nurses must also be aware of any/all changes to local PrEP protocols and action these in a timely manner.
<p>Responsibilities of professional manager(s)</p>	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.</p>

Documentation

<p>Authorisation of supply</p>	<p>Senior nurses working in Sexual Health Clinics within NHS Grampian ,NHS Highland and NHS Shetland can be authorised to supply the medicine(s) specified in this PGD by their Professional Line Manager/Consultant.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1).</p> <p>A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional’s records, or as agreed locally.</p>
<p>Record of supply</p>	<p>An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of supply • Individuals name and CHI/AN number (DOB if CHI not available) • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained

	<ul style="list-style-type: none"> • The name, dose, form, route of the medicine supplied • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine • Record of any adverse effects • Inform GP if have patient consent <p>Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:</p> <ul style="list-style-type: none"> • NaSH – Sexual Health Electronic Patient Record as well as STISS coding • Individual service specific systems.
<p>Audit</p>	<p>All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.</p>
<p>References</p>	<p>Electronic Medicines Compendium http://www.medicines.org.uk Emtricitabine/Tenofovir disoproxil 200 mg/245 mg film-coated tablets (Glenmark brand) – Date of revision of text 19/03/21, accessed 19/08/21.</p> <p>British National Formulary https://about.medicinescomplete.com/ accessed 19/08/21.</p> <p>BHIVA/BASHH guidelines on the use of HIV pre-exposure prophylaxis (PrEP) 2018 http://bhiva.org/PrEP-guidelines.aspx</p> <p>PrEP in Scotland Report http://www.hivscotland.com/our-work/prep-in-scotland/</p> <p>PrEP IMPACT TRIAL: https://www.prepimpacttrial.org.uk/ https://www.scottishmedicines.org.uk/medicines-advice/emtricitabinetenofovir-disoproxil-truvada-fullsubmission-122517/</p> <p>BHIVA–BASHH Position Statement on PrEP in UK Appendix 1: Practical guidance for healthcare workers 160505 Practical PrEP guidance (bhiva.org)</p> <p>PROUD Study Results, Key Messages, Questions and Answers Results MRC CTU Proud</p> <p>BHIVA/BASHH/BIA Adult HIV Testing guidelines 2020 https://www.bhiva.org/HIV-testing-guidelines</p>



Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Emtricitabine 200mg/Tenofovir Disoproxil 245mg Tablets By Sexual Health Nurses Working Within NHS Grampian, NHS Highland and NHS Shetland For Pre Exposure Prophylaxis (PrEP) To Individuals At Risk Of HIV Infection – Version 2.1

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____



Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

