

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

## PATIENT GROUP DIRECTION (PGD)

# Supply of combined hormonal contraceptive transdermal patch in Rotherham, Doncaster and South Humber (RDaSH) NHS Foundation Trust

## Version Number 2.0

Change History		
Version and Date	Change details	
Version 1 April 2020	New template	
Version 1.1 November 2020	Minor rewording and highlighting of contents caution section relating to individuals for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.  Acute porphyria added to exclusion criteria.	
Version 1.2 March 2022	Addition of vaping/use of e-cigarettes where reference to smoking within PGD Following exclusion criteria updated from 3-6 weeks to less than 6 weeks: 'Not breastfeeding and less than 6 weeks post-partum with other risk factors for venous thromboembolism (VTE).	
Version 2.0 April 2023	Updated template – amended references and minor editing and wording changes/clarifications.	

## PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	April 2023
Review date	September 2025
Expiry date:	March 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2022.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Vice President, General Training
	Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee
	Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Advisory Service (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS Northeast London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

## ORGANISATIONAL AUTHORISATIONS.

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	Medical Director	#	21/02/23
Stephen Davies	Chief Pharmacist	Davis	8/3/23
Kate McCandlish	Interim Director of Nursing	mals	1/3/23
Anil Rajpal	Senior pharmacist	& fRaysel	1/3/23
Tina Proctor	Nurse Consultant Senior representative of professional group using the PGD	Thet	21/3/23

## **Committee Approval:**

NAME	DATE
Medicines Management Committee	17/02/2023

Date of Implementation	22/03/2023
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## 1. Characteristics of staff

	O
Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.
	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy.
	Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory.
	Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - <a href="mailto:eLfH PGD elearning programme">eLfH PGD elearning programme</a>
	The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	<ul> <li>Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for contraception supply.</li> <li>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</li> </ul>
Ongoing training and competency	<ul> <li>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required.</li> <li>Organisational PGD and/or medication training as required by employing Trust/organisation.</li> </ul>
The decision to supply any medication rests with the individual registered health professional	
who must abide by the PGD and a	any associated organisational policies.

## 2. Clinical condition or situation to which this PGD applies

Clinical condition or situation	Contraception
to which this PGD applies	• Contraception
Criteria for inclusion	<ul> <li>Individual (age from menarche to up to 50 years) presenting for contraception.</li> <li>Consent given.</li> </ul>
	A recent, accurate blood pressure recording, and BMI should be documented for all individuals prior to first CHC supply and repeated for each subsequent supply. In exceptional circumstances, such as the COVID-19 pandemic, where a remote consultation has to take place and it is not possible to obtain a BP or BMI then the 'FSRH clinical advice to support provision of effective contraception during the COVID-19 outbreak' or equivalent should be used for assessing whether a client is suitable to receive treatment under this PGD. See <a href="https://www.fsrh.org/documents/fsrh-ceu-clinical-advice-">https://www.fsrh.org/documents/fsrh-ceu-clinical-advice-</a>
Criteria for exclusion	to-support-provision-of-effective/
Criteria for exclusion	<ul> <li>Consent not given.</li> <li>Individuals under 16 years of age and assessed as not competent using Fraser Guidelines.</li> <li>Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>Established pregnancy. Note - risk of pregnancy with a negative pregnancy test is not an exclusion</li> <li>Known hypersensitivity to an active ingredient or to any constituent of the product - see Summary of Product Characteristics</li> <li>Less than 21 days after childbirth (for deliveries over 24 weeks gestation)</li> <li>Breastfeeding and less than six weeks postpartum.</li> <li>Not breastfeeding and less than 6 weeks post-partum with other risk factors for venous thromboembolism (VTE).</li> <li>Individuals aged 50 years and over.</li> <li>Significant or prolonged immobility.</li> </ul>
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	<ul> <li>Cardiovascular disease</li> <li>Individuals aged 35 years or more who currently smoke or stopped smoking less than one year ago (this includes vaping and the use of e-cigarettes)</li> <li>Body Mass Index (BMI) equal to or greater than 35kg/m²</li> <li>Blood pressure greater than 140/90mmHg or controlled hypertension</li> <li>Multiple risk factors for cardiovascular disease (CVD) (such as smoking (includes vaping/use of e-cigarettes), diabetes, hypertension, obesity and dyslipidaemias)</li> <li>Current or past history of ischaemic heart disease, vascular disease, stroke or transient ischaemic attack</li> <li>Current or past history of venous thromboembolism</li> <li>Complicated valvular or congenital heart disease e.g., pulmonary hypertension, history of subacute bacterial</li> </ul>

- endocarditis
- First degree relative with venous thromboembolism which first occurred when they were under 45 years of age
- Known thrombogenic mutations e.g., factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies
- Cardiomyopathy with impaired cardiac function
- Atrial fibrillation

## **Neurological Conditions**

- Current or past history of migraine with neurological symptoms including aura at any age
- Migraine without aura, when first attack occurred on a method of contraception containing an oestrogen

### **Cancers**

- Past or current history of breast cancer
- Undiagnosed breast mass (for initiation of method only)
- Carrier of known gene mutations associated with breast cancer e.g., BRCA1or 2
- Malignant liver tumour (hepatocellular carcinoma)

### **Gastro-intestinal Conditions**

- Viral hepatitis, acute or flare (for initiation only)
- Benign liver tumour (hepatocellular adenoma)
- Severe decompensated cirrhosis
- Gallbladder disease; currently symptomatic or medically managed.
- Any bariatric or other surgery resulting in malabsorption.
- Cholestasis (related to past combined hormonal contraceptive use)

### Other conditions

- Imminent planned major surgery (CHC should be stopped at least 4 weeks prior to planned major surgery or expected period of limited mobility).
- Diabetes with end organ disease (retinopathy, nephropathy, neuropathy)
- Positive anti-phospholipid antibodies (with or without systemic lupus erythematosus)
- Organ transplant, with complications
- Known severe renal impairment or acute renal failure
- Acute porphyria

### **Medicines**

- Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them.
- Interacting medicines (other than enzyme inducers), including any medicines purchased – see current British National Formulary (BNF) <u>www.bnf.org</u> or individual product SPC <u>http://www.medicines.org.uk</u>

## Cautions including any relevant action to be taken

• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made

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	<ul> <li>and documented.</li> <li>If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.</li> <li>Discuss with appropriate medical/independent nonmedical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.</li> <li>Individuals taking lamotrigine should be advised that CHC may interact with lamotrigine; this could result in reduced seizure control or lamotrigine toxicity.</li> <li>Offer LARC to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.</li> <li>If an individual is known to be taking a medication which is known to be harmful to pregnancy a highly effective form of contraception is recommended. Highly effective methods include the LARC method is unacceptable/unsuitable and a CHC is chosen, then an additional barrier method of contraception is advised. See FSRH advice.</li> </ul>
Action to be taken if the	Explain the reasons for exclusion to the individual and
individual is excluded or	document in the consultation record.
declines treatment	<ul> <li>Record reason for declining treatment in the consultation record.</li> </ul>
	<ul> <li>Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

## 3. Description of treatment

o. Description of treatment	
Name, strength & formulation of drug	Each 20cm <sup>2</sup> transdermal patch contains 6 mg norelgestromin and 600 micrograms ethinylestradiol
Legal category	POM
Route of administration	Transdermal
Off label use	Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).  This PGD includes inclusion criteria, exclusion criteria and
	dosage regimes which are outside the market authorisation for many of the available products, but which are included within FSRH guidance. Specifically, the use of tailored CHC regimens is outside the manufacturer's licence, as is use in those under 18 years or over 45 years of age, but their use is supported by the Faculty of Sexual & Reproductive Healthcare (FSRH). The regimes detailed within this PGD are permitted
	under this PGD.  Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the

local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management.

Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.

## Dose and frequency of administration

- Each patch releases 33.9 mcg ethinylestradiol and 203mcg norelgestromin per 24 hours over a seven-day period.
- FSRH guidance states that CHC can either be used following a standard or tailored regime.
- Individuals should be given information about both standard and tailored CHC regimens to broaden contraceptive choice.

## **Regimes**

• The regimes which can be advised are detailed below:

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Type of regimen	Period of CHC use	Hormone (patch) free interval	
	Standard use		
Standard use	21 days (3 patches)	7 days	
	Tailored use		
Shortened hormone-free interval	21 days (3 patches)	4 days	
Extended use (tri- cycling)	9 weeks (9 patches)	4 or 7 days	
Flexible extended use	Continuous use (≥21 days) of active patches until breakthrough bleeding occurs for 3–4 days	4 days	
Continuous use	Continuous use of active patches	None	

- A single patch applied at the same time each week for seven days starting on day 1-5 of the menstrual cycle with no need for additional protection.
- The patch can be started at any time after day five if it is reasonably certain that the individual is not pregnant.
   Additional contraception is then required for seven days after the patch is applied.
- Thereafter the dosage regime detailed above should be followed. Individuals should have access to clear information (either written or digital) to support tailored CHC use.
- When starting or restarting the CHC as quick start after levonorgestrel emergency contraception, additional contraception is required for 7 days, and a pregnancy test should be performed 21 days after the last unprotected sexual intercourse.
- In line with FSRH guidance individuals using hormonal

	<ul> <li>contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e., use of condoms or abstain from intercourse) should be advised until fully effective. For CHC patches this is for 7 days after re-starting this method.</li> <li>For guidance on changing from one contraceptive method to another, and when to start after an abortion and postpartum, refer to the FSRH guidance.</li> </ul>
Duration of treatment	<ul> <li>For as long as the individual requires CHC and has no contraindications to its use</li> </ul>
Quantity to be supplied	<ul> <li>Supply of up to twelve months (maximum 52 patches) in appropriately labelled original packs.</li> <li>For all supplies ensure the individual is aware that the regimen to be taken may not be reflected in the dosage information printed on the product packaging or within the supplied PIL – ensure full details of regimen to be followed are supplied.</li> </ul>
Storage	Medicines must be stored securely according to national
Drug interactions	guidelines.  All concurrent medications, including those purchased should be considered for interactions.
	A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website <a href="www.medicines.org.uk">www.medicines.org.uk</a> the BNF <a href="www.bnf.org">www.bnf.org</a> and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/">https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</a>
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website: <a href="https://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="https://www.bnf.org">www.bnf.org</a>
	The following possible adverse effects are commonly reported with CHC (but may not reflect all reported adverse effects):  Nausea Breast tenderness Headache and migraine Temporary disturbances of bleeding patterns Change in mood including depression Fluid retention Change in libido Skin changes including acne  Specific adverse events associated with transdermal patch
	CHC include:  • Localised skin irritation
	Serious adverse effects - these are less common, but the risks should be discussed with the individual:  • Venous thromboembolic events (VTE)  • Arterial thromboembolic disorders (including ischaemic

## heart disease) Strokes (e.g., transient ischaemic attack, ischaemic stroke, haemorrhagic stroke) Hypertension Healthcare professionals and individuals/carers are Management of and reporting encouraged to report suspected adverse reactions to the procedure for adverse Medicines and Healthcare products Regulatory Agency reactions (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Record all adverse drug reactions (ADRs) in the individual's clinical record. Report via organisation incident policy. Provide manufacturer's information leaflet (PIL) provided Written information and with the original pack further advice to be given to Individuals should be informed about the superior individual effectiveness of LARC. Individuals should be provided with written information or a link to a trusted online resource to support safe, effective CHC use. Explain mode of action, side effects, and benefits of the medicine. Advise individual on how to apply the patch, remove the patch and how patch changes should be managed. The patch should be applied immediately upon removal from the protective sachet. To prevent interference with the adhesive properties of the transdermal patch, no creams, lotions or powders should be applied to the skin area where the transdermal patch is to be applied. Advise the individual that the patch should not be applied to irritated or broken skin. The patch should not be put on the breasts. Advise individual that only one patch should be worn at any one time. Advise individual on action to take if the patch becomes partially or fully detached and any incorrect use. Advise on patch disposal - the disposal label from the outside of the sachet should be peeled open. The used transdermal patch should be placed within the open disposal label so that the sticky surface covers the shaded area on the sachet. The disposal label should then be closed sealing the used transdermal patch within. The patch should be disposed of in normal household waste. Used transdermal patches should not be flushed down the toilet nor placed in liquid waste disposal systems. Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken noting that the risks of using CHC could outweigh the benefits. Serious symptoms: the individual should stop taking the CHC and seek urgently medical help if they experience calf swelling, heat or pain in the calf, shortness of breath, chest pain or haemoptysis. The individual should seek advice if they experience their first ever

Reference Number: 2 Valid from: 1<sup>st</sup> April 2023 Review date: September 2025 Expiry date: 30<sup>th</sup> March 2026 migraine or develops aura with existing migraine.

	<ul> <li>Individuals should be advised that current use of CHC is associated with a small increased risk of breast cancer which reduces with time after stopping CHC.</li> <li>Individuals should be advised that current use of CHC for more than 5 years is associated with a small increased risk of cervical cancer the risk of which reduces over time after stopping CHC and is no longer increased by about 10 years after stopping.</li> <li>Individuals should be advised that current use of CHC is associated with an increased risk of VTE/ATE.</li> <li>Individuals using CHC should be advised about reducing periods of immobility during travel.</li> <li>Individuals trekking to high altitudes (above 4500 m or 14 500 feet) for periods of more than 1 week may be advised to consider switching to a safer alternative contraceptive method.</li> <li>Individuals should be advised to stop CHC and to switch</li> </ul>		
	to an alternative contraceptive method at least 4 weeks prior to planned major surgery or expected period of limited mobility.		
	Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs)		
	Ensure the individual has contact details of local service/sexual health services.		
	Advise individual to seek advice from a pharmacist, doctor		
	or other prescriber before starting any new medications		
	including those purchased.		
Advice / follow up treatment	<ul> <li>The individual should be advised to seek medical advice in the event of an adverse reaction.</li> </ul>		
	The individual should be encouraged to tell all clinicians		
	that they are taking the supplied medication in the event of		
	other medication/s being prescribed.  The individual to seek further advice if they have any		
	The individual to seek further advice if they have any		
	concerns Review annually.		
Records	ecord:		
Recolus	The consent of the individual and		
	<ul> <li>If individual is under 13 years of age record action</li> </ul>		
	taken		
	If individual is under 16 years of age document     appoint uning France guidelines. If not competent		
	capacity using Fraser guidelines. If not, competent record action taken.		
	<ul> <li>If individual over 16 years of age and not</li> </ul>		
	competent, record action taken		
	Name of individual, address, date of birth		
	GP contact details where appropriate		
	Relevant past and present medical history, including medication, smoking status and family history.		
	<ul> <li>Examination finding including BMI and blood pressure.</li> </ul>		
	Any known allergies		
	Name of registered health professional		
	Name of medication supplied		

- Date of supply
- Dose supplied
- Quantity supplied including batch number and expiry date in line with local procedures.
- Advice given, including advice given if excluded or declines treatment
- Details of any adverse drug reactions and actions taken
- Advice given about the medication including side effects, benefits, and when and what to do if any concerns
- Any follow up and/or referral arrangements made
- Any supply outside the terms of the product marketing authorisation
- Recorded that supply is via Patient Group Direction (PGD)

Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.

All records should be clear, legible and contemporaneous.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

## 4. Key references

## Key references (accessed September 2022)

- Electronic Medicines Compendium http://www.medicines.org.uk/
- Electronic BNF https://bnf.nice.org.uk/
- NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2
- Faculty of Sexual and Reproductive Healthcare (2019, amended 2020) Combined Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/guidance/documents/guidance/documents/guidance/documents/guidance/documents/guidance/documents/guidance/guidanc
- FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) <u>FSRH CEU Guidance: Drug</u> <u>Interactions with Hormonal Contraception (May 2022)</u> -<u>Faculty of Sexual and Reproductive Healthcare</u>
- Faculty of Sexual and Reproductive Healthcare (2019, amended November 2020) Combined Hormonal Contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/">https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/</a>
- Faculty of Sexual and Reproductive Healthcare (2016, amended 2019) UK Medical Eligibility Criteria for Contraceptive Use.

https://www.fsrh.org/documents/ukmec-2016/

 Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Quick Starting Contraception (April 2017) <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/</a>

## Appendix A – example registered health professional authorisation sheet

**PGD Name/Version: CHC transdermal Patch** 

Valid from: April 2023 Expiry: March 2026

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

## Registered health professional

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

## I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct. Designation **Signature** Name **Date**

## **Authorising manager**

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of RDaSH NHS Foundation Trust for the abovenamed health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

## Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

This information will be retained by the Chief Pharmacist of RDASH NHS Foundation Trust.