Patient Group Direction for the supply of Combined transdermal Patch (CTP)

Title of patient group direction	**The supply of the Combined Transdermal Patch for contraception (CTP)**
Approved at	NMP/PGD Group
PGD approved / valid from	December 2018
Review date	September 2020
Expiry date	December 2021
Clinical area(s) where PGD applies	Sexual Health, HIV and Outreach Services - North Yorkshire and York Within contraceptive and sexual health clinics/services, and sexual health outreach services and locations
Identified Lead for monitoring / review and contact details	Wendy Billsborough – Advanced Nurse Specialist

CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Reviewed Document	Yes
If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation	Expired UKMEC updated New FRSH CHC guidance Tailored regimes

List of persons involved in the consultation process. (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed).	Wendy Billsborough – Advanced Nurse Specialist Dr Frances Baker – CaSH Dr Alison Chorlton – Lead Nurse Sexual Health Carolyn Boardall, Directorate Pharmacist

CLINICAL CONDITION	
Condition	• Contraception
Inclusion criteria	• Female clients (age from menarche to 50 years) requesting contraception and who have no contraindications
Exclusion criteria	**Personal Characteristics and Reproductive History:** • Pre-pubertal with no established menstrual cycle • Child 12 years or under • Child under 16 years not considered competent under Fraser guidelines • Pregnancy • Undiagnosed abnormal vaginal bleeding • Postpartum – less than 21 days • Breast-feeding and less than 6 weeks postpartum • Not breast feeding and 3-6 weeks post-partum with other risk factors for VTE (such as immobility, transfusion at delivery, BMI ≥30 kg/m2, postpartum haemorrhage, immediately post-caesarean delivery, pre-eclampsia or smoking) • Known allergy to constituent of the CTP • Endometrial hyperplasia • Weight 90 kg or above • Patient wishes to see a doctor **Cardiovascular Disease:** • BMI equal to or greater than 35kg/m^2 • Systolic blood pressure greater than 140 mmHg or diastolic blood pressure greater than 90mmHg • Controlled hypertension • Vascular disease – includes coronary heart disease presenting with angina; peripheral vascular disease presenting with intermittent claudication; hypertensive retinopathy and transient ischaemic attacks • Smoking or use of e-cigarettes (currently or within the last year) if 35 years of age or over

	• Two or more risk factors for cardiovascular disease such as smoking, diabetes, hypertension, obesity (BMI greater than 30kg/m^2 and dyslipidaemias • Two or more risk factors for venous thromboembolism such as BMI over 30kg/m^2, age over 35, smoking, cancer, chronic inflammatory bowel disease (ulcerative colitis or Crohn's disease) • Hyperlipidaemia • Current or past history of ischaemic heart disease, stroke or transient ischaemic attack • Current or past history of venous thromboembolism • First degree relative with venous thromboembolism under 45 years of age • Known thrombogenic mutations e.g. Factor V Leiden, prothrombin mutation Protein S, Protein C, and antithrombin deficiencies • Significant or prolonged immobility including planned major surgery • Complicated valvular or congenital heart disease e.g. with pulmonary hypertension, . or history of subacute bacterial endocarditis • Atrial fibrillation • Cardiomyopathy with impaired cardiac function • Diabetes with end organ disease: nephropathy, retinopathy, neuropathy or other vascular disease **Neurological Conditions** • Past or current migraine with aura at any age • Migraine without aura, first attack when on oestrogenic contraception **Cancers** • Breast cancer – current or past history of • Undiagnosed breast mass (for initiation of method only) • Carriers of known gene mutations associated with breast cancer e.g. BRCA 1 • Liver tumours - benign hepatocellular (adenoma) and malignant (hepatoma)

	• Known or suspected malignant endometrial tumours or other oestrogen dependent neoplastic disorders **Gastro-intestinal Conditions** • Active liver disease • Gall bladder disease - symptomatic • Cholestasis related to past combined hormonal contraceptive use • Current malabsorption e.g. due to acute Crohn's • Pancreatitis or history thereof if associated with severe hypertriglyceridemia **Other conditions** • Positive antiphospholipid antibodies with or without Systemic lupus erythematosus (SLE) • Raynaud's disease – secondary, with lupus anticoagulant • Complicated organ transplant • Interacting medicines – see current British National Formulary (BNF) on interactions. This includes the use of enzyme inducers in the past 4 weeks, some over the counter and herbal preparations • Acute porphyria • Sickle cell disease • History of haemolytic uraemic syndrome or history during pregnancy of pruritus, chorea, cholestatic jaundice or deterioration of otosclerosis, pemphigoid gestationis
Action if excluded	• Discuss and offer an alternative contraceptive method • If CTP is the preferred choice refer to doctor or independent nurse prescriber or GP if more appropriate in an outreach setting • Document action in patient's records

Action for patients not wishing to receive care under the PGD	• Record the refusal in the client record Refer to appropriate doctor or independent nurse prescriber if client agrees

DESCRIPTION OF TREATMENT			
Name of Medicine	Transdermal patch delivering 203 micrograms of norelgestromin and 33.9 micrograms of ethinylestradiol in 24 hours		
Legal Classification	Prescription Only Medicine (POM)		
Licensing information			
	Is the medicine licensed for the intended use?		Yes licensed for contraception
	Does it have a black triangle status?		**NO**
Form	Transdermal Patch		
Strength	Each transdermal patch contains 6mg Norelgestromin and 600 micrograms of ethinyl estradiol		
Dose	• The CTP releases 33.9 micrograms of ethinyl estradiol and 203 micrograms of norelgestromin per 24 hours • A single patch is applied once a week, at the same time every week for three weeks. The fourth week of the cycle is a seven day patch free interval Or discuss tailored regimes and tricycling and a 4 day patch free interval		
Frequency	• Single patch applied once a week starting on day 1-5 of the menstrual cycle with no need for additional contraception • CTP can be quick started at any time after day 5		

if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 7 days after starting.

- When starting after levonorgestrel emergency contraception, additional contraception is required for 7 days.
- After the use of ulipristal emergency contraception, CTP should not be started for 5 days, then started/restarted. Additional contraception is required for a further 7 days
- For guidance on switching from another contraceptive method to the CTP refer to FSRH guidance on 'switching or starting methods of contraception'
- CTP can be safely started immediately at any time after abortion. Additional contraception is required for 7 days if started 5 days or more after abortion.
- CTP can be started from day 21 postpartum in women who are not breast feeding and are without additional risk factors for VTE. Additional precautions are required if CTP is started 21 days or more after childbirth.
- CTP should not be used by women who have risk factors for VTE until 6 weeks postpartum
- CTP can be started at 6/52 postpartum in women who are breastfeeding

See FSRH contraception after pregnancy guidance for risk factors for VTE postpartum,

- Discuss both standard and tailored regimes with a 4 day hormone free interval and advice tailored use is off-label but supported by FSRH

Type of regimen	**Period of CHC use**	**Hormone-free interval**
Standard use:	21 days (3 patches)	7 days
Tailored use		
Shortened	21 days (3 patches)	4 days

	hormone-free interval:		
	Extended use (tricycling):	9 weeks (9 patches used consecutively)	4 or 7 days
	Flexible extended use:	Continuous use (≥21 days) of patches, until breakthrough bleeding occurs for 3-4 days.	4 or 7 days
	Continuous use:	Continuous use of patches.	None
Route	Transdermal – Avoid the breast area and any skin that is sore or irritated		
Total Treatment Quantity	• Initial supply of up to 6 months considering patient preference and anticipated use • Subsequent supply of up to 12 months considering patient preference and anticipated use • It may be appropriate to provide a more limited supply (e.g. 3 - 6 months) for women who would benefit from returning for an earlier or more frequent follow-up. Consider potential changes to medical history, family history and lifestyle factors which could move an individual's risks to an UKMEC 3 or 4 category e.g. BMI, raised blood pressure, smoking, migraine and age. • Younger age may also indicate the need for more frequent review.		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	• Check any medicines in appendix 1 of the BNF under oestrogens and progestogens • For drugs affected by the CTP see FSRH CEU guidance Drug Interactions with Hormonal Contraception **If in doubt contact Medicines Information for advice ext 5960**		

	• Women taking lamotrigine should be advised that CTP may interact with lamotrigine; this could result in reduced seizure control or lamotrigine toxicity. The risks of using CTP could outweigh the benefits. • The efficacy of CTP may be affected by enzyme inducing drugs or herbal preparations concomitant and within the previous 4 weeks	
Adverse Reactions (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information)	**Most commonly reported:** • Nausea • Breast tenderness • Fluid retention • Headache • Temporary irregular bleeding • Mood changes • Skin irritation at patch site **Serious Symptoms:** Severe calf pain, swelling or heat Shortness of breath, chest pain or haemoptysis First ever migraine or increased frequency or severity of existing migraines **Health Risks**: *Venous thromboembolism (VTE):* The risk of VTE with CTP is approximately doubled but	**Treatment of adverse reactions** Document the adverse reaction in the patient's medical records. The GP should also be informed with client consent Stop using the CTP and seek immediate medical attention and advice Any serious adverse drug reactions should be reported to the MHRA by the yellow card scheme. Guidance on its use is available in the BNF or can be accessed via www.mhra.gov.uk/yellowcard

	the absolute risk is still very small and less than that in pregnancy. Risk will depend on an individual's baseline risk of thromboembolism. Risk is highest in the first year of using CTP and upon re-starting after a break of 4 weeks or more. *Cervical Cancer:* The risk appears to increase with long-term CTP use (more than 5 years) After CTP use ends the risk declines, returning to that of never-users 10 or more years after stopping *Breast Cancer:* The frequency of diagnosis of breast cancer is very slightly increased among CTP users. As breast cancer is rare in women under 40 years of age this increase is small in relation to the overall risk of breast cancer. Risk doesn't increase with duration of use and disappears within 10 years of stopping CTP use. The risk among women with a family history of breast cancer is not increased further by using CTPs	

Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Explain the mode of action, efficacy, benefits, risks, how to use and possible side effects • Discuss the effect of any conditions that increase the risk of thrombosis • Advise that VTE risk is increased with periods of extended travel and to reduce periods of immobility during flights of more than 3 hours • Advise re signs and symptoms of a thrombosis • Refer to web based FPA CTP patient information. Offer the product patient information leaflet (PIL) • Advise re any need for additional contraception on starting CTP. • Advise that additional contraception/abstinence is required when quick starting/continuing CTP after emergency contraception: After levonorgestrel for 7 days After ulipristal wait for 5 days before starting the CTP then additional precautions for 7 days • Advise to return for a pregnancy test 3 weeks after quick starting if pregnancy could not be excluded at the time of starting CTP • If supplied off label this needs to be clarified with the patient • Provide clear advice to support tailored use. Explain that tailored CTP regimens are as safe as traditional 21/7 regimens, can reduce the frequency of withdrawal bleeds and can reduce withdrawal symptoms associated with the HFI; however unscheduled bleeding is common • Encourage continuation of the method for at least 3 months before considering an alternative • Advise re interacting medicines including St Johns Wort • Advise re action to take if the patch detaches, the individual forgets to change the patch or there is extension of the patch free interval – refer to FPA leaflet • Advise to return or seek professional advice if they are experiencing troublesome side effects, have a significant new health event, start new

	medication, wish to discontinue CTP or to discuss alternative methods. Provide verbal information supported by access to written information on signs and symptoms that should alert the need for medical advice (Refer to 'Risks' section in FPA CTP leaflet) • Advise on safe sex
Follow up action	Women should be routinely reviewed on an annual basis; routine follow-up, including annual recording of B/P and BMI may be achieved without a face-to-face consultation. Women with certain existing medical conditions may benefit from attending more frequently or from face to face follow-up .
Storage	• Locked drugs cupboard or briefcase for outreach use
Records to be Kept	The following minimum details should be documented in full in the clients records: • Assessment of client request in relation to the supply of CTP • Past and present medical and family history, including drug history • Menstrual, coital and obstetric history • Weight, BMI and blood pressure • Any known allergies • Date • Completion of CTP proforma • On the prescription, record drug name and amount supplied • Advice given to patient concerning indications for follow up and review • Route of administration • That CTP was supplied under a PGD • Discussion with patient if supply was made outside the product licence (off-label) • Information and advice given (see written and oral advice) • Any communication with other health care professionals

	• Name of health professional supplying the medicine (may be electronic)
Audit Arrangements	As per current Trust PGD Policy
References	• Faculty of Sexual & Reproductive Healthcare Clinical Guidance; Combined Hormonal Contraception CEU (2011)(2018-draft) • British National Formulary – www.bnf.org.uk • The Electronic Medicines compendium – www.medicines.org.uk/emc/ • Policy and Procedure for the supply and/or administration of medicines under a patient group direction (2015). York Teaching Hospital • Faculty of Sexual & Reproductive Healthcare Clinical Guidance, The UK Medical Eligibility Criteria for Contraceptive Use (2009) • Faculty of Sexual & Reproductive Healthcare (2017) Quick Starting Contraception • Faculty of Sexual and Reproductive Healthcare (2017) Drug Interactions with Hormonal Contraception • Faculty of Sexual & Reproductive Healthcare (2015) Problematic Bleeding with Hormonal Contraception • Faculty of Sexual and Reproductive Healthcare (2017) Contraception after pregnancy • Faculty of Sexual and Reproductive Healthcare (2016) Switching or starting methods of contraception • Faculty of Sexual and Reproductive Healthcare (2017) Emergency contraception
Competency Requirements (attach any competency frameworks / documents)	The Nurse must be authorised by name under the current version of this PGD before working to it <u>Education, training, qualifications and competencies</u>:

	• Sexual health Nurse • Clinical competence in sexual history taking. • Completion of the Trust PGD awareness session or Trust HUB e-learning. • Knowledge of the FSRH combined hormonal contraception guidance (2018- draft) • Knowledge base of the interaction of CTP with other drugs, and other exclusions and contraindications for issuing the CTP • Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health. • Assessment will be undertaken by the Lead Nurse/ANS or designated PGD assessor, who will be practising as an independent prescriber • Maintain professional accountability with the NMC and ensure continual professional development • Receive clinical supervision and/or audit of case notes on an ongoing basis • Evidence of relevant continuing professional development identified through clinical supervision and appraisal • Regular attendance and participation in educational clinical governance sessions and nurse updates • Ensure keeps up to date with any changes to FSRH guidance relevant to this PGD

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	Wendy Billsborough	Wendy Billsborough	4/10/2018
Clinical Director Lead Approval	Ian Fairley		16/10/2018
Directorate Pharmacy Lead Approval	JILL McENANEY	Jim McGinley	19.12.2018

PGD Approved by the NMP/PGD Group

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		19.12.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		21/12/2018 .

Authorisation to work within the PGD

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

The PGD must be easily accessible in the clinical setting.

Notes to the NMP/PGD Authorising staff

- Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy)
- You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD
- Using a PGD is not a form of prescribing

Staff authorised to work under this PGD	
Ward / Department	Sexual Health, HIV and Sexual Health Outreach services
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed competency training

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	October 2015
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Approved by	NMP/PGD Group
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