

Patient Group Direction

for the supply of

a Progestogen-only Oral Contraceptive Pill (POP)

in Bridgewater Community Healthcare NHS Foundation Trust

Version 3

Change History

Version Number	Details of Main Changes	Date
3	<p>Addition of Foundation Trust logo and references to it.</p> <p>General updates to PGD format and requirements to match NICE standard PGD template. Updates in accordance with FSRH Clinical guidance on progesterone-only contraception (March 2015). Sign off sheet is now individual for each staff member.</p> <p>Note: Practitioners are reminded that they must read the full document and be aware of its contents before signing up to it.</p>	November 2016

Developed and Approved by

Doctor	Name	Dr Karen Slade
	Designation	Executive Medical Director
	Signature	<i>Karen Slade</i> Date 1/12/2016
Pharmacist	Name	Jo Bark-Jones
	Designation	Deputy Head of Medicines Management
	Signature	<i>Jo Bark-Jones</i> Date 22/12/2016
Nurse	Name	Elaine Unsworth
	Designation	Lead Nurse Sexual Health Service Warrington
	Signature	<i>Elaine Unsworth</i> Date 30/11/16

Acknowledgements

Name	Designation
Pippa Brough	Consultant & Clinical Director of Warrington Sexual Health Service
Jill Mathieson	Sister Contraception and Sexual Health Service Wigan
Sarah Quinn	Head of Medicines Management
Julie MacAngus	Non Medical Prescribing Lead

Authorised on behalf of Bridgewater Community Healthcare NHS Trust	Name	Dorian Williams
	Designation	Assistant Director of Clinical Governance and Clinical Quality
	Signature	<i>Dorian Williams</i> Date 28/11/16

Requirements of the registered healthcare professional working under the PGD	
Qualifications and professional registration	<p>You must be authorised by name under the current version of this PGD before working to it</p> <ul style="list-style-type: none"> Registered nurse / midwife / health visitor with current registration with the Nursing and Midwifery Council, employed by Bridgewater Community Healthcare NHS Foundation Trust (Bridgewater) <p>OR</p> <ul style="list-style-type: none"> Healthcare Professionals who are legally entitled to administer / supply medicines via PGDs who have a current Health Professions Council (HPC) registration and are employed within Bridgewater.
Initial training	<ul style="list-style-type: none"> Received appropriate training approved by Bridgewater and is competent in all aspects of the use of progestogen only oral contraceptive preparations and its administration including contraindications and the recognition and treatment of anaphylaxis Has undertaken appropriate training and holds a recognised Higher Education Institute accredited Sexual and Reproductive Health qualification Received training to undertake administration and supply of medicines under PGDs in accordance with organisational Medicines and PGD policies. Has undertaken appropriate training in Safeguarding Children and is aware of local procedures for acting on any child protection issues including the name and contact details of their nominated lead for child protection Has received training in Safeguarding Vulnerable Adults and is aware of local procedures for acting on any vulnerable adult protection issues including the name and contact details of their nominated lead for the protection of vulnerable adults.
Ongoing training and competency	<ul style="list-style-type: none"> Receives updates in cardiopulmonary resuscitation (CPR) and anaphylaxis in accordance with the organisational Resuscitation Policy Maintains own level of updating with evidence of Continued Professional Development (CPD) and / or Post Registration and Practice (PREP) requirements. <p>It is the responsibility of the individual to keep up-to-date with CPD. Practitioners should be constantly alert to any changes to the recommendations for the preparation listed including subsequent recommendations from the Department of Health (DH) and Faculty of Sexual & Reproductive Healthcare and adverse drug reaction (ADR) bulletins.</p> <p>Information in such documents supersedes information within the PGD and should be followed. However if this advice affects the inclusion / exclusion criteria, then the practitioner MUST seek a Patient Specific Direction (PSD) until the PGD has been revised.</p>
Additional requirements	<ul style="list-style-type: none"> Immediate access to adrenaline 1 in 1,000 injection Facilities to summon help in case of anaphylaxis Facilities for resuscitation to be available.

Clinical details	
Indication	Prevention of pregnancy in females of child-bearing age, who are aged 13 years or over.
Inclusion criteria	<ul style="list-style-type: none"> • Informed consent obtained. • Females aged 13 years or over requiring contraception. • Females under 16 years of age assessed and documented as competent under the Fraser Guidelines follow Bridgewater Community Healthcare NHS Foundation Trust Safeguarding Children Policy. • Suitability assessed by taking/updating history • First issue in women requesting contraception and following full discussion choose to use the POP • Repeat issue for client who is already using the POP without any concerns. <p>Note: Client must understand the method of contraception, missed pills routine, be aware of emergency contraception and how to obtain it, and aware of the possible need for condom use and possible side effects of the product.</p>
Exclusion criteria	<ul style="list-style-type: none"> • No valid consent • Any contraindications to progestogen only contraceptives. • Hypersensitivity to any of the components of the progestogen only oral contraceptive preparation. • Females under 13 years of age. Follow the Safeguarding Policy and refer. • Pregnancy or suspected pregnancy. • Current or past history of breast cancer. • Current or history of ischaemic heart disease or cerebrovascular disease/stroke including transient ischemic attack (TIA). • Past or current history of breast/genital carcinoma. • Known or suspected progestogen-dependent tumours or any condition that may be affected by the hormones within the POP. • Severe liver disease or hepatic cell tumours (Note: Hepatitis is rated 1 in UKMEC 2016). • Porphyria.
(continued overleaf)	

<p>Exclusion criteria Continued../</p>	<p>Anyone taking drugs/medications (including prescription, over the counter preparations, herbal, recreational drugs and dietary supplements) that may interact with the progestogen only pill including: Aprepitant, atazanavir, barbiturates, boceprevir, bosentan, carbamazepine, ciclosporin, crizotinib, dabrafenib, efavirenz, elvitegravir, eslicarbazepine, griseofulvin, lamotrigine, nelfinavir, nevirapine, oral anticoagulants, orlistat, oxcarbazepine, perampanel, phenytoin, primidone, rifabutin and rifampicin (rifamycins), ritonavir, rufinamide, selegiline, St John's Wort (<i>Hypericum perforatum</i>), sugammadex, terbinafine, tizanidine, topiramate, ulipristal, vemurafenib, voriconazole.</p> <p>Exclusion under this PGD does not necessarily mean the medicine is contraindicated, but it would be outside its remit and another form of authorisation will be required.</p>
<p>Cautions</p> <p>(continued overleaf)</p>	<p>Each tablet should be taken approximately the same time of day, if delayed more than 3 hours (12 hours for Cerazette®, Cerelle®, Zelleta®, Aizea®) additional contraception required. See Appendix 3 for details.</p> <p>The effectiveness of the POP may be considerably reduced by interaction with certain drugs – always check. See also exclusion criteria and advice to patient sections.</p> <p>The incidence of ectopic pregnancies for progestogen-only oral contraceptive users is 5 per 1000 woman-years, which is higher than for women using other contraceptive methods but similar to the incidence for women not using any contraception. Up to 10% of pregnancies reported in clinical studies of progestogen-only oral contraceptive users are extra-uterine. Although symptoms of ectopic pregnancy should be watched for, a history of ectopic pregnancy need not be considered a contraindication to use of this contraceptive method. Vaginal bleeding and abdominal pain are typical symptoms of an ectopic pregnancy. Women reporting these symptoms should be evaluated.</p> <p>Norgeston® SPC states that if there is a history of ectopic pregnancy or one fallopian tube is missing the use of Norgeston® should be carefully considered.</p> <p>Norgeston® SPC states that persistent functional ovarian cysts may occur, most are asymptomatic and resolve spontaneously although may cause pelvic pain or dyspareunia.</p> <p>Diarrhoea and vomiting may interfere with absorption of pill – see Appendix 3 for details.</p> <p>History of cholasma gravidarum, client should avoid exposure to the sun or ultraviolet radiation whilst taking this preparation.</p> <p>Drugs affected by contraceptive hormones Women taking medicines affected by contraceptive hormones such as antidiabetics, diuretics, anticoagulants, may require monitoring of drug levels or effect when starting, changing or stopping hormonal contraception – refer to doctor to ensure appropriate follow-up.</p>

Cautions Continued.. /	Refer to BNF and SPC for complete list of drug interactions. If the patient is taking any concomitant medicines or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. (For drug interactions see Appendix 1 of BNF or the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the medicine is given. If the requirements of this PGD cannot be complied with the patient must be referred.
Action to be taken if excluded	<ul style="list-style-type: none"> • Refer if appropriate • Document findings and action taken in patient's record
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • Advise patient of possible consequences of refusing treatment and of alternative sources of treatment • Document refusal and advice given in patient's record • Offer alternative treatment where appropriate and inform referrer.

Details of Medicine	
Name, form and strength of medicine	<p>This patient group direction is for the issuing of the following progestogen only oral contraceptive preparations according to the relevant Area Prescribing Committee formulary recommendations :</p> <p>Tablets for oral use</p> <p>Brands include:</p> <ul style="list-style-type: none"> • Norethisterone 350micrograms tablets - Micronor[®] /Noriday[®] 28 tablet pack • Levonorgestrel 30micrograms tablets - Norgeston[®] 35 tablet pack • Etonodiol diacetate 500micrograms tablets - Femulen[®] 28 tablet pack • Desogestrel 75micrograms tablets - Cerazette[®] / Cerelle[®] /Zelleta[®] /Aizea[®] 28 tablet pack <p>Refer to the local medicines formulary for the appropriate brand and choice.</p>
Legal category	Prescription Only Medicine (POM)
Black Triangle▼	No

<p>Unlicensed / off label use</p> <p>(continued overleaf)</p>	<p>Use of medicines outside their product licences in a PGD should be justified by current best clinical practice and be evidence-based. The practitioner should comply with the following:</p> <ul style="list-style-type: none"> • Explain the risks/benefits to the client • Explain to the client that it is being used out of licence • Obtain the client's verbal consent • Document these issues have been discussed and that consent has been given <p>It is now accepted practice to use POPs outside the terms of their product licence for certain situations, in accordance with the Faculty of Sexual and Reproductive Healthcare (FSRH) guidance (see Appendix 2).</p> <p>This guidance varies from the SPCs in relation to:</p> <ul style="list-style-type: none"> • the advice in the event of missed pill and vomiting and diarrhoea. • initiation following miscarriage or abortion. • switching from non oral combined hormonal contraceptives is not covered in the SPCs for Micronor[®], Noriday[®], Femulen[®]. • Norgeston[®] and Femulen[®] are licensed for initiation on day 1. Cerazette[®], Cerelle[®], Zelleta[®], Aizea[®] is licensed for initiation on day 1 further details in relation to start day and start day and amenorrhoea vary from the FSRH guidance. • advice for extra additional precautions varies when Norgeston[®], Noriday[®], Femulen[®], Cerelle[®] and Cerazette[®] are started postpartum after day 21. • advice regarding switching from intra-uterine device (IUD) or levonorgestrel-releasing system is not included in the SPC for Femulen[®], Norgeston[®], Noriday[®] • advice regarding switching from IUD is not included in the SPC for Cerazette[®], Cerelle[®], Zelleta[®], Aizea[®]. <p>Quick Start - Starting contraception at the time a woman requests contraception rather than waiting for the next menstrual cycle. If a woman prefers to delay starting contraception or if she is concerned about potential risks she may wait until her next period or until the risk of pregnancy has been excluded.</p> <p>Previous Faculty guidance has advised that contraceptive methods can be started at any point in the menstrual cycle if a practitioner is reasonably certain the woman is not currently pregnant or at risk of pregnancy.</p>
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<p>Unlicensed / off label use Continued.../</p>	<p>If starting POP immediately after POEC, additional barrier contraception or avoidance of sex for 2 days is recommended. If starting POP immediately after ulipristal acetate (UPA, EllaOne®), delay starting POP for at least 5 days and then use additional precautions for a further 48 hours/2 days. Also a pregnancy test should be performed no sooner than 3 weeks after the last episode of unprotected sex irrespective of whether a bleed has occurred.</p>
<p>Route / method of administration</p>	<p>Tablets for oral use</p>
<p>Dose and frequency</p>	<p>One tablet daily every day without a break, within 3 hours (12 hours for Cerazette®, Cerelle®, Zelleta®, Aizea®) at the same time each day.</p> <p>Every day preparations. Commence the next pack the day after finishing the first pack.</p> <p>(See Summary of Product Characteristics, unlicensed / off label use section and Appendix 2 for timing of initiation details and Appendix 3 for “missed” pills).</p>
<p>Supply</p>	<p>Maximum 3 x 28 tablets first supply Maximum 3 x 35 tablets first supply as appropriate for product Maximum 12 x 28 tablets for established users Maximum 12 x 35 tablets for established users as appropriate for product</p>
<p>Maximum or minimum treatment period</p>	<p>Continuously as appropriate.</p>
<p>Adverse effect</p> <p>*NB This should be weighed against the benefits</p>	<p>Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list</p> <ul style="list-style-type: none"> • Irregular bleeding, amenorrhoea. • Nausea and vomiting. • Breast tenderness. • Dizziness, headache and depression. • Changes in body weight and libido. • Possible small increased risk of breast cancer*. • Skin disorders. <p>ADRs must be recorded and the patient’s General Practitioner (GP) informed.</p> <p>Report all serious suspected reactions in adults and in children (under 18 years) via the Yellow Card reporting scheme. www.mhra.gov.uk/yellowcard</p>

<p>Handling / use / storage / labelling / disposal</p>	<ul style="list-style-type: none"> • Store in a locked medicines cabinet at room temperature (25°C or less) • Store in original packaging • Protect from light • Disposal should be by incineration as per organisational waste management policy and according to current waste regulations • The European Commission Labelling and Leaflet Directive applies to all medicines supplied under PGDs. They must be labelled with: <ul style="list-style-type: none"> ○ the clients name ○ the date of supply ○ the clinic address
<p>Records to be kept</p>	<ul style="list-style-type: none"> • Record that valid informed consent was given • Name of patient, address, date of birth, current contact number and GP • Past and present medical history including medicine history and any allergies • Signature, / e-signature designation and printed name of member of staff who supplied the medicine • Date of issue • Name of medicine and dose, strength form and quantity supplied • Manufacturer of medicine / brand, batch number and expiry date • Advice given both verbal and written • Advice given for interacting medicines, conditions and side effects • Advice given if excluded or declines treatment • Record how the patient's central record or GP surgery record will be updated (where the client gives permission) • Details of any ADRs and actions taken • Record supplied via PGD • Any leaflet supplied • Any use outside Product Licence • Date next appointment is due • Special instructions (e.g. if additional contraception is required for a specific period of time) • Fraser rule competence document if client under 16 years of age or record valid parent/guardian consent • Clinic contact details issued <p>All records should be clear, legible and contemporaneous.</p> <p>The information should be recorded in the patient record as per local documentation requirements.</p> <p>A computer or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes</p>

Patient Information

Advice to patient

- Explain treatment and course of action
- Discuss side effects and administration
- The patient must seek medical advice if they experience any hypersensitivity reaction
- Potential health risks and benefits of the method
- The effectiveness of a progestogen only oral contraceptive may be considerably reduced by interaction with certain drugs – always check with prescriber or pharmacist. See also exclusion criteria and drug interaction section.
- Ensure the manufacturers' patient information leaflet (PIL) is in the box prior to issue
- Additional contraceptive precautions are not required during or after courses of antibiotics that do not induce liver enzymes. Although women should be advised about the importance of correct contraceptive practices during periods of illness. However if the antibiotics (and/or the illness) cause vomiting or diarrhoea then the usual additional precautions relating to these conditions should be observed
- An alternative contraceptive method is recommended during and for at least 4 weeks after treatment with an enzyme inducing drug
- Missed pill advice and advice in case of diarrhoea and vomiting (refer to Appendix 3)
- If any adverse symptoms occur advise client to seek medical advice that day
- Women taking oral contraceptives may be at an increased risk of deep vein thrombosis during travel involving long periods of immobility (over 5 hours). The risk may be reduced by appropriate exercise during the journey and possibly by wearing graduated compression hosiery
- Barrier protection to protect against sexually transmitted infections also required if appropriate
- If cervical cytology is required refer to appropriate practitioner or make an appointment with appropriate practitioner

(continued overleaf)

<p>Advice to Patient continued../</p>	<ul style="list-style-type: none"> • Diet and exercise advice for BMI outside of normal range if applicable • Current Family Planning Association (FPA) leaflets on POP and Emergency Contraception to be discussed and given to client. Provide explanation of any discrepancies in written material and reinforce current advice/information <p>Give contact numbers for local Sexual and Reproductive Health Clinics, FPA Helpline and NHS Direct.</p> <p>Smoking Cessation if applicable –</p> <p>General advice: 0800169 0 169 National Quitline: 0800 002200</p> <p>Bridgewater Community Healthcare NHS Foundation Trust Local Numbers (for smoking cessation services):</p> <p>Ashton, Leigh & Wigan 0500 7867669 or 01942 482539 Halton: 01928 593043 St Helens: 01744 814837 Warrington: 01925 843713</p>
<p>Follow-up advice to be given to the patient/carer</p>	<ul style="list-style-type: none"> • As appropriate. <p>Three months for first time issue, 4 weeks to 12 weeks for clients under 16 years of age, depending on individual needs. Up to 12 months for established users, or sooner at client's request.</p> <ul style="list-style-type: none"> • Discuss advice and provide information on follow-up to the patient • If patient is not eligible for treatment under this PGD refer to GP or other service as appropriate.

Appendices

Appendix 1 – Key references

- NMC (2010) Standards for medicines management www.nmc-uk.org
- NMC (2008) The Code. Standards of conduct, performance and ethics for nurses and midwives
- Electronic Medicines Compendium (EMC) - SPC for progestogen-only contraceptive pill brands on www.emc.medicines.org.uk accessed 1 November 2016
- Electronic BNF available on www.bnf.org.uk accessed 1st November 2016
- Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit - Progestogen-only Pills March 2015 (updated January 2016)
- Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Unit –Clinical Guidance- Quick starting contraception September 2010
- Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guidance – Drug Interactions with Hormonal Contraception, Clinical Effectiveness Unit January 2011 (updated January 2012)
- Faculty of Sexual and Reproductive Healthcare (FSRH) – UK Medical Eligibility Criteria for Contraceptive Use – 2016.

Appendix 2

Faculty of Sexual Healthcare & Clinical Guidance Clinical Effectiveness (CEU) Guidance – Recommendation for timing of initiation of progestogen-only pills

CEU GUIDANCE

Table 3 Recommendations for timing of initiation of progestogen-only pills		
Circumstance	Recommendations for timing of Initiation	Additional contraception advised
General initiation	Progestogen-only pills (POPs) can be started up to and including Day 5 after the start of the menstrual cycle.	NO
	POPs can also be started at any other time if the clinician is reasonably certain that the woman is not pregnant and there has been no risk of conception.	YES, for 48 hours
	If the woman is amenorrhoeic, the clinician must be reasonably certain that the woman is not pregnant and there is no risk of conception.	YES, for 48 hours
Postpartum	POPs initiated up to Day 21 postpartum.	NO
	POPs initiated after Day 21 postpartum.	YES, for 48 hours
Following miscarriage or abortion	POPs initiated on the day of surgical abortion or second part of medical abortion or immediately following miscarriage.	NO
	POPs initiated >5 days after surgical abortion or second part of medical abortion or miscarriage.	YES, for 48 hours
Switching from another method of contraception		
Combined hormonal contraception (CHC)	Can be initiated immediately if CHC has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there has been no risk of conception.	NO
Progestogen-only pill (POP)	Can be initiated immediately if POP has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there has been no risk of conception.	NO
Progestogen-only implant	Can be initiated immediately if the implant has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there has been no risk of conception.	NO
Progestogen-only injectable	If the woman's previous method was an injectable she should start POPs when the repeat injection would have been given or before.	NO
Levonorgestrel-releasing intrauterine system (LNG-IUS) or copper-bearing intrauterine device (IUD)	POP initiation at time of IUD removal (avoid intercourse or use condoms in addition for 7 days before the removal of an IUD).	YES, for 48 hours
	POP initiation at least 2 days before the removal of an IUD.	NO
	POP initiation at time of LNG-IUS removal.	NO
Barrier method (male condom, female condom, cap or diaphragm)	Can be initiated immediately if barrier method has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception.	YES, for 48 hours unless POP initiated on Days 1–5 of menstrual cycle

Appendix 3: Advice for women who are late or missed taking the Progestogen-only Pill

CEU GUIDANCE

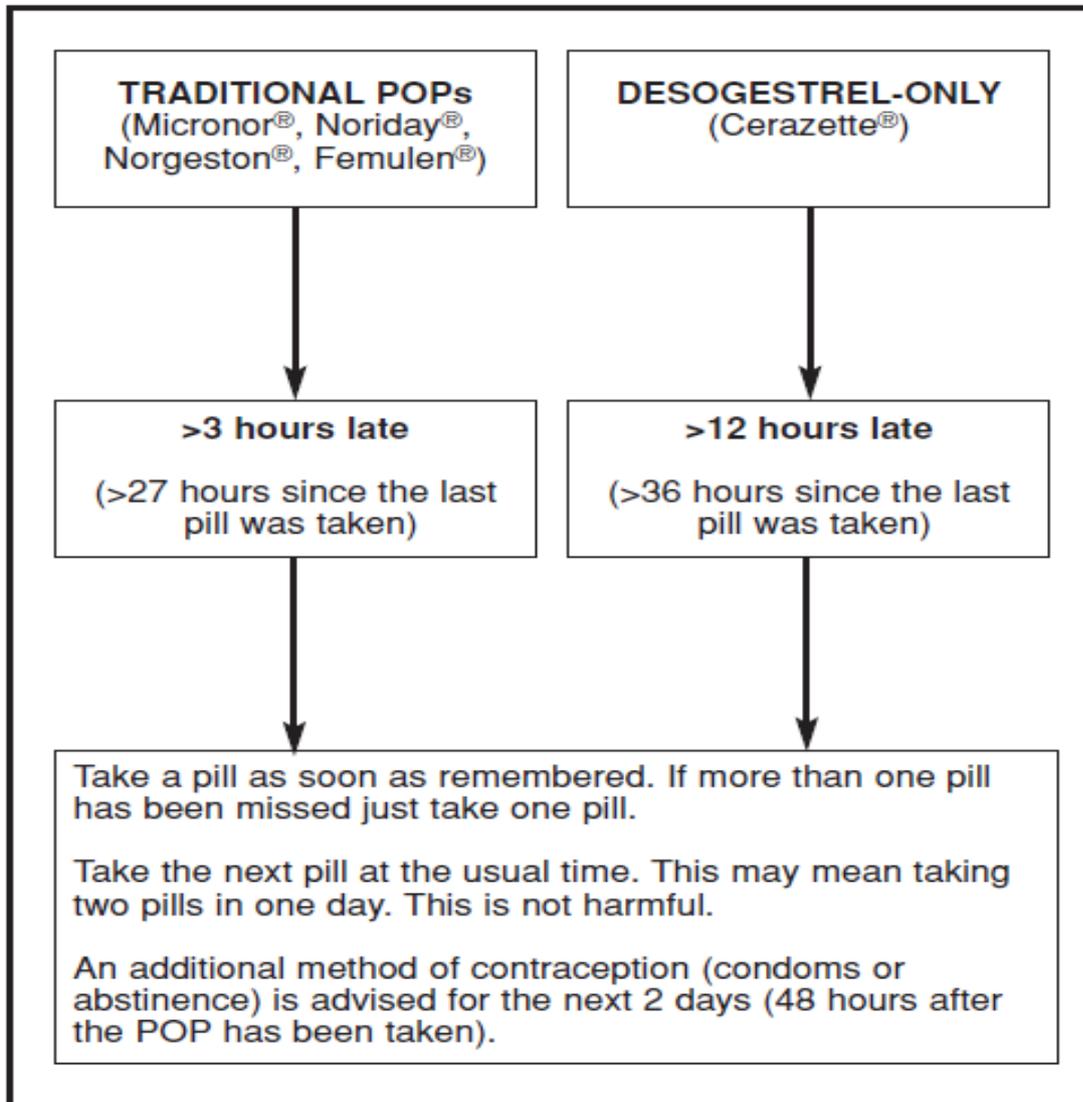


Figure 1 Advice for women who miss or are late taking the progestogen-only pill (POP)

Diarrhoea and Vomiting

If a woman vomits within 2 hours of taking a POP then she should be advised to take another pill as soon as possible.
If she is now >3 hours (or >12 hours for a desogestrel-only pill) late, continues to vomit or has very severe diarrhoea she will need to follow the missed pill rules if she is sexually active (Figure 1) above.

Appendix 4: Health Professional's agreement to practice

**Patient Group Direction for the supply of
a Progestogen-only oral Contraceptive Pill
in Bridgewater Community Healthcare NHS Foundation Trust**

PGD: 005, Version Number: 3, Expiry Date:31st December 2018, **Start Date:** 1st January 2017

Individual practitioner authorisation sheet

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 (PGDs) 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.

Practitioner

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.

Signed..... **Date**.....
Name (Print - capitals).....
Designation.....
Service name
Contact telephone number
Contact email address.....

Authorising manager

Manager to give authorisation on behalf of Bridgewater Community Healthcare NHS Foundation Trust for the named health care professional who has signed the PGD.

Signed..... **Date**.....
Name (Print - capitals).....
Designation.....
Contact telephone number
Contact email address.....

Note to authorising manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD.

Managers must keep a service database of all staff signed up to use this PGD according to the Medicines Policy and SOPs.