Patient Group Direction for the administration of medroxyprogesterone acetate injection 150mg/ml (DMPA)	
Title of patient group direction	The administration of : Medroxyprogesterone acetate injection 150mg/mL (DMPA)-progestogen only depot
Approved at	NMP / PGD Group
PGD approved / valid from	June 2019
Review date	February 2022
Expiry date	June 2022
Clinical area(s) where PGD applies	YorSexual Health, HIV and Outreach Services
Identified Lead for monitoring / review and contact details	Wendy Billsborough, YorSexualhealth

CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	No
Revised 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	Exclusions updated in line with UKMEC 2016 Addition of guidance to give repeat depo in relation to late injections as in line with FSRH guidance
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 Alison Chorlton, Lead Nurse Sexual Health Dr Ian Fairley, Clinical Director Lead Carol Belt, Principal Pharmacy Technician

CLINICAL CONDITION	
Condition	Contraception
Inclusion criteria	Female clients (age from menarche up to 50 years) requesting contraception and who have no contraindications Women aged less than18 years can have depo medroxyprogesterone acetate (DMPA) as a first line option after all other options have been discussed and considered unsuitable or unacceptable
Exclusion criteria	**Personal Characteristics and Reproductive History:** • Pre-pubertal with no established menstrual cycle • Patient 12 years or under • Patients over 50 years of age • Children under 16 years not considered competent under Fraser guidelines • Known or suspected pregnancy • Known allergy to any constituent of the injection **Cardiovascular Disease:** • Significant multiple (2 or more) risk factors for cardiovascular disease e.g. diabetes, hypertension, hyperlipidaemias, smoking and obesity (BMI over 30) • Hypertension with vascular disease • Current and history of ischaemic heart disease • Current and history of stroke/transient ischaemic attack • Diabetes with end organ disease (nephropathy, retinopathy, neuropathy or other vascular disease)

	Cancers • Known or suspected hormone-dependent malignancy of breast or genital organs • Malignant hepatocellular carcinoma **Liver** • Presence or history of severe hepatic disease where liver functions test have not returned to normal • Benign hepatocellular adenoma **Other conditions** • Systemic Lupus Erythematosus (SLE) with positive or unknown antiphospholipid antibodies • Interacting medicines – see current BNF on interactions • Significant risk factors for osteoporosis including known current osteoporosis or osteopenia, long term corticosteroid or anticonvulsant treatment, severe malabsorption syndromes. Low BMI (less than 18.5) or eating disorders e.g. anorexia nervosa or bulimia. Also alcohol abuse, smoking, vitamin D deficiency, inactivity, coeliac disease, first degree family history of osteoporosis. • Acute porphyria • Unexplained abnormal vaginal bleeding
Action if excluded	• Discuss/offer an alternative contraceptive method • If depo medroxyprogesterone (DPMA) is the preferred choice refer to doctor/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/independent nurse prescriber if client agrees

<table>
<tr><th colspan="4">DESCRIPTION OF TREATMENT</th></tr>
<tr><td>Name of Medicine</td><td colspan="3">Medroxyprogesterone Acetate</td></tr>
<tr><td>Legal Classification</td><td colspan="3">POM</td></tr>
<tr><td>Licensing information</td><td colspan="3">Best practice advice given by the Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC)

This PGD allows for unlicensed use by extending the window for administration:

• Administration at 10 weeks
• Administration to 14 weeks
• Administration after 5 days post partum if not breast feeding
• Administration before 6 weeks post partum if breast feeding

Also when given after emergency contraception
<table>
<tr><td>Is the medicine licensed for the intended use?</td><td>√YES</td><td></td></tr>
<tr><td>Does it have a black triangle status?</td><td></td><td>√NO</td></tr>
<tr><td>Does it have a Risk Minimisation Measures (RMM) recommendation</td><td></td><td>√NO</td></tr>
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</td></tr>
<tr><td>Form</td><td colspan="3">Injection</td></tr>
<tr><td>Strength</td><td colspan="3">150mg/mL</td></tr>
<tr><td>Dose</td><td colspan="3">150mg every 13 weeks</td></tr>
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Route	• Deep IM injection into the gluteal (preferred site) or deltoid muscle • Consider deltoid route or S/C DMPA (sayana press) if there is concern about ability to deliver IM due to body weight • Shake well before administration • Do not massage the injection site after administration
Frequency	• Start on day 1- 5 of the menstrual cycle with no need for additional protection • DMPA can be started at any time as quick start if it is reasonably certain that the individual is not pregnant (off-label use). Additional contraception is then required for 7 days after starting. • Quick starting can be considered after levonorgestrel emergency contraception if all other bridging methods are not appropriate or acceptable. The lack of evidence regarding use in early pregnancy should be explained. Additional contraception is required for 7 days. • A pregnancy test is advised 3 weeks after any oral emergency contraception • Quick starting can be considered 5 days or more after the use of ulipristal acetate (UPA) if all other bridging methods are not appropriate or acceptable. It is recommended that hormonal contraception should not be used for five days, and non- hormonal methods used for 5 days then started/restarted. Extra precautions should then be used for a further 7 days • DMPA should be repeated at 13 week intervals after the last injection. A repeat injection can be given up to 3 weeks early (10 weeks) or up to 1 week late (14 weeks) with no additional contraceptive precautions required. • If the individual presents after 14 weeks and there has been no unprotected sexual intercourse since week 14, DMPA may be given (off-label) with additional contraceptive

	precautions for a further seven days. • If the interval from the preceding injection is greater than 14 weeks (13 weeks plus 7 days) and unprotected sexual intercourse has occurred there is a pregnancy risk. The injection can be given after EC if a bridging method is not acceptable. Refer to the FSRH progestogen only injection guidance on late injections for management – see appendix 1 • For guidance on changing from one contraceptive method to another, and when to start after an abortion and post-partum refer to FSRH guidelines, 'Switching or starting methods of contraception' and 'Contraception after pregnancy'
Total Treatment Quantity	For as long as the individual requires DMPA up to the age of 50 years and has no contraindications to use of DMPA The risks and benefits of using DMPA should be re-evaluated every visit In women with significant risk factors for osteoporosis, other methods should be considered
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 progestogens Depo-provera injection is unaffected by enzyme inducers For drugs affected by progestogens see Faculty of Sexual and Reproductive Healthcare (FSRH) Guidance: Drug Interactions with Hormonal Contraception NB: Use of DMPA in women taking ciclosporin may result in the development of toxic levels of ciclosporin. **If in doubt contact Medicines Information for advice ext 5960**

• **Adverse Reactions**	• DMPA is well tolerated • Hypersensitivity reactions are uncommon. • Most commonly reported: • Headache, dizziness • Disturbance of bleeding patterns/amenorrhoea, • Changes in mood, • Weight gain particularly in women under 18 with a BMI of 30 or over • Loss of libido, • Hot flushes, • Acne, alopecia, • Delay in return to fertility after stopping the medication • Injection site reaction – listed as mild to moderate • DMPA is associated with a small loss of density (BMD) which is usually recovered after discontinuation. • Reduction in BMD occurs in the first 2-3 years of use and then stabilises. • There is no available evidence on the effect of DMPA on long-term fracture risk • Possible weak association between current use of DMPA and breast cancer • Weak association between cervical cancer and use of DMPA • Diabetes – glucose tolerance decreased	**Treatment of adverse reactions** If necessary seek appropriate emergency advice and assistance Document the adverse reaction in the patient's medical records. The GP should also be informed with client consent Any serious adverse 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

	• See Summary of Product characteristics for full details	
Advice to Patients: Written and Oral advice (This should include the provision of a patient information leaflet)	• Refer to web based FPA progestogen injection patient information. Offer the product patient information leaflet (PIL) • Explain mode of action, side effects and benefits and when to return for the repeat injection • Advise re potential injection site reactions (see adverse reactions section) and not to massage the site after the injection • Advise about the risks of the injection including failure rates (approx. 0.2% in first year of use and a typical failure rate of 6%), health risks and serious side effects and the actions to be taken • Advise re effect on BMD, diet and weight bearing exercise to improve bone strength • Advise re possible effect on glucose tolerance and diabetics may need additional monitoring • Advice regarding any need for additional contraception – refer to frequency section for relevant guidance when switching and post-partum. • Advise to return for a pregnancy test no sooner than 3 weeks after UPSI if quick starting after oral EC or other situations in which pregnancy cannot be excluded • Inform the patient if supplied off-label • Offer condoms and advise on safer sex practices • Ensure individual knows what to do if her medical condition changes in the future. Ensure individual has the contact details of the service	

Storage	Locked medicines cupboard or briefcase for outreach use – store below 25 °C
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 administration of DMPA • Past and present medical and family history, including drug history and risk factors for osteoporosis • Consent of the individual • Weight, BMI and blood pressure at initial consultation and annually • Any known allergies • Date • Completion of the injection assessment proforma • On the prescription, record drug name and dose. • Site of injection • Batch number and expiry date • Route of administration • That DMPA was administered under a PGD • Details of any side effects or adverse drug reactions and what action taken • Information and advice given (see written and oral advice) • Follow up • Any communication with other health care professionals • Record of name of staff administering/supplying medicine (May be electronic)
Audit Arrangements	As per current Trust PGD Policy

References	• Faculty of Sexual & Reproductive Healthcare Clinical Guidance; Progestogen-only injectable Contraception CEU (updated 2019) • British National Formulary – www.bnf.org.uk • Manufacturer's Summary of Product Characteristics – Depo –Provera 150mg/1ml. Pfizer Ltd. 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 (2016) • Faculty of Sexual & Reproductive Healthcare Clinical Guidance, Quick Starting Contraception, CEU (2017) • Faculty of Sexual and Reproductive Healthcare Clinical Guidance; Drug Interactions with Hormonal Contraception (Jan 2017) • 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 Education, training, qualifications and competencies: • 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 Progestogen Only injection guidance (2014 – updated 2019) and completion of the relevant e-learning for health module • Knowledge base of the interaction of DMPA with other drugs, and other exclusions and contraindications for issuing DMPA

	• 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. • Receiving clinical supervision and/or audit of case notes on an ongoing basis • Evidence of Commitment to continuing professional development in sexual health as identified through clinical supervision and appraisal • Regular attendance and participation in educational clinical governance sessions and nurse updates • Maintain professional accountability with the NMC and ensure continual professional development • Has undergone regular updating in basic life support and anaphylaxis • It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their individual scope of practice

AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF: **Medroxyprogesterone**			
PGD Development / Review Team – responsible for PGD content			
Title	**Name**	**Signature**	**Date**
Lead Author	Wendy Billsborough	Wendy Billsborough	20/5/2019.
Clinical Director Lead Approval	Dr Ian Fairley		22/05/2019
Directorate Pharmacist Lead Approval	Jill McEnaney	Jill McEnaney	14.6.2019
PGD Approved by the NMP/PGD Group			
Title	**Name**	**Signature**	**Date**
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		17.06.2019
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes	Stuart Parkes.	17/6/2019.

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- medroxyprogesterone	
Ward / Department	Sexual Health
Professionals to whom this Patient Group Direction applies	Qualified nurses working within the YorSexualHealth service 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:	February 2018
Version:	3
Approved by	NMP/PGD Group
Review date:	February 2021

Faculty of sexual and reproductive healthcare advice in relation to late progestogen – only contraceptive injections.

Appendix 1

Timing of Injection	Has UP SI occurred?	Is there a risk of pregnancy	Can EC be offered?	Can the injection be given?	Is additional contraception required?	Is a pregnancy test required?
Up to 14 weeks since last DMPA injection	**Yes**	**No**	**N/A**	**Yes**	**No**	**No**
14 weeks + 1 day or more since last IM or SC DMPA injection	**No** (no sex or used barrier method)	**No**	**N/A**	**Yes**	**Yes** (7 days after injection)	**No**
	Yes, but only in the last 5 days (sex that occurs up to week 14 is protected)	**Yes**	**Yes**. Consider Cu- IUD or LNG EC. The effectiveness of UPA EC could theoretically be reduced by residual circulating progestogen.	**Yes** (If bridging method not acceptable) After LNG EC injection can be given immediately. After UPA EC, delay injection for 5 days.	**Yes** (until 7 days after injection)	**Yes** >3 weeks since last episode of UPSI
	Yes- multiple episodes < 5 days ago and > 5 days ago	**Yes**	**No**	**Yes** (if bridging method not acceptable).	**Yes** (until 7 days after injection)	**Yes**, prior to administering the injection and > 3 weeks since last episode of UPSI
	Yes- multiple episodes>5 days ago and <3 weeks ago.	**Yes**	**No**	**Yes** (if bridging method not acceptable).	**Yes** (until 7 days after injection)	**Yes**, prior to administering the injection and > 3 weeks since last episode of UPSI
	Yes – multiple episodes >3 weeks ago	**Yes**	**No**	Perform a pregnancy test and if negative administer injectable	**Yes** (until 7 days after injection)	**Yes**, prior to administering the injection

Faculty of sexual and reproductive healthcare advice in relation to late progestogen – only contraceptive injections.