Patient Group Direction for the administration and / or supply of subcutaneous medroxyprogesterone acetate (Sayana Press) (MPA) injection 104mg/0.65ml by registered nurses and for supply to individuals to self-administer

Title of patient group direction	The administration or supply of subcutaneous medroxyprogesterone acetate (MPA) injection for contraception
Approved at	NMP/PGD Group
PGD approved / valid from	May 2018
Review date	January 2021
Expiry date	May 2021
Clinical area(s) where PGD applies	Sexual heath and HIV outreach services within contractive and sexual health clinics, and in sexual health outreach services/locations
Identified Lead for monitoring / review and contact details **(should this be where signatures are)**	Wendy Billsborough

CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)	
New Document	Yes
Revised Document	No
If the PGD is revised what revisions were required and for what reasons	To allow for supply and administration of lower dose subcutaneous medroxyprogesterone and for self - administration by patient

e.g. change in medical procedures or change in legislation	
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 Alison Chorlton – Lead Nurse Sexual Health Dr Ian Fairley, Clinical Director Lead Carol Belt, Principal Pharmacy Technician Medicines Information Jill McEnaney, Directorate Pharmacist

CLINICAL CONDITION	
Condition	Contraception
Inclusion criteria	Female clients (age from menarche up to 50 years) requesting contraception and who have no contraindications Due to its possible effect on bone mass density women aged less than18 years can have subcutaneous medroxyprogesterone acetate (MPA) 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, smoking, obesity (BMI over 30) and hyperlipidaemias • 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** • 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 or secondary amenorrhoea due to anorexia nervosa or marathon running , alcohol abuse , family history of osteoporosis, • Acute porphyria • Unexplained abnormal vaginal bleeding
Action if excluded	Discuss/offer an alternative contraceptive method If subcutaneous medroxyprogesterone acetate(MPA) 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	Discuss/offer an alternative contraceptive method If medroxyprogesterone (MPA) 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

<table>
<tr><th colspan="4">DESCRIPTION OF TREATMENT</th></tr>
<tr><td>Name of Medicine</td><td colspan="3">Medroxyprogesterone Acetate (Sayana Press)</td></tr>
<tr><td>Legal Classification</td><td colspan="3">Prescription only medicine (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:

• Supply and administration at 10 weeks
• Supply and administration to 14 weeks
• Supply and administration after 5 days post partum if not breast feeding
• Supply and administration before 6 weeks post partum if breast feeding</td></tr>
<tr><td></td><td>Is the medicine licensed for the intended use?</td><td>YES- see above for 'off-label' use</td><td></td></tr>
<tr><td></td><td>Does it have black triangle status</td><td></td><td>NO</td></tr>
<tr><td></td><td>Does it have a Risk Minimisation Measures (RMM) recommendation</td><td></td><td>NO</td></tr>
<tr><td>Form</td><td colspan="3">Injection</td></tr>
<tr><td>Strength</td><td colspan="3">104 mg in 0.65ml</td></tr>
<tr><td>Dose</td><td colspan="3">104 mg every 13 weeks</td></tr>
<tr><td>Frequency</td><td colspan="3">• Start on day 1-5 of the menstrual cycle with no need for additional protection</td></tr>
</table>

	• MPA 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 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, then started/restarted. Extra precautions should then be used for a further 7 days • MPA 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 interval from the preceding injection is greater than 14 weeks (13 weeks plus 7 days) and there has been no unprotected sexual intercourse since week 14, MPA 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, refer to appropriate doctor/non- medical prescriber • 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'
Route	Subcutaneous Injection When supplied for self-administration advise the individual to follow the manufacturer's instructions and specifically: • Follow the manufacturer's guidance for administration • Shake the syringe/vial vigorously before administration • To ensure that the full injection is given, the medication should be injected slowly over approximately 5-7 seconds with the needle pointing downwards • Do not expel the air bubble • Inject into the upper anterior thigh or the anterior abdomen, avoiding bony areas or the umbilicus • Do not massage the site after the administration of the injection
Total Treatment Quantity	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 1 prefilled 0.65ml injection to be administered by nurse or by the patient every 10 - 14 weeks as long as there is no contraindication And Between 1 and 4 prefilled 0.65ml injections may be supplied to the patient to take away once competency in self administration has been demonstrated and documented on the YSH Sayana press competency form
Interactions with other medicines	Check any medicines in appendix 1 of the BNF under

(This must include all potentially serious interactions listed in the BNF)	progestogens Sayana press (MPA) 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 MPA 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 (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)	MPA is well tolerated Hypersensitivity reactions are uncommon Most commonly reported: • Headache, dizziness • Disturbance of bleeding • Injection site reactions • Changes in mood • Insomnia • Weight change • Abdominal pain, nausea • Loss of libido • Acne • Delay in return to fertility after stopping the medication • MPA is associated with a small loss of density (BMD) which is usually recovered after discontinuation • Possible weak association between	**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 The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so

	current use of MPA and breast cancer • Weak association between cervical cancer and use of MPA • Diabetics- glucose tolerance decreased 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 the individual not to massage the site after the injection • Teach individual how to self-administer according to manufacturer's instructions • Advise individual on safe disposal of sharps according to local policy • Advise individual about need to return for repeat injection if she experiences any difficulty with administration • Women should be re-evaluated periodically as clinically appropriate at least every year to determine if Sayana Press is still the best option for them • Advise about the risks of the injection including failure rates, health risks and serious side effects and the actions to be taken • Advise re diet and weight bearing exercise to improve bone strength • 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
Follow up action	• Individual to return to clinic if she has any concerns • Individuals to be re-evaluated at least yearly to determine if Sayana Press is still the best option for them
Storage	• Locked medicines cupboard or briefcase for outreach use – store below 25 °C
Records to be Kept	• Assessment of client request in relation to the supply of MPA • Any reason for exclusion and action taken • Any known allergies • Relevant past and present medical and family history, including drug history • Consent of the individual • Date • Completion of MPA injection proforma • Record demonstration of how to administer the injection • Completed competency form signed by assessing Nurse and the patient • On the prescription, record drug name and quantity supplied and administered • Batch number and expiry date • That the injection was supplied or administered under a PGD • Route of administration • Site of injection • Advice given • Follow up • Details of any adverse drug reactions and what action taken • Any communication with other health care professionals

	• Record of name of health professional supplying the medicine (may be electronic) • Any supply made outside the product licence
Audit Arrangement	As per current Trust PGD Policy
References	• Faculty of Sexual & Reproductive Healthcare (2014) Progestogen-only injection • Medical Eligibility Criteria for Contraceptive Use (2016) • British National Formulary – www.bnf.org.uk • Manufacturer's Summary of Product Characteristics - Sayana press 104mg/0.65ml. Pfizer Ltd. The Electronic Medicines compendium – www.medicines.org.uk/emc/ • Faculty of Sexual and Reproductive Healthcare (2013) New Product review from clinical effectiveness Unit. Subcutaneous Depo medroxyprogesterone Acetate (Sayana Press) • 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 (2017) Quick Starting Contraception • Faculty of Sexual and Reproductive Healthcare (2017) Drug Interactions 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 /	The Nurse must be authorised by name under the current version of this PGD before working to it

documents)	<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 Progestogen Only injection guidance (2014) and completion of the relevant e-learning for health module • Knowledge base of the interaction of MPA with other drugs, and other exclusions and contraindications to MPA • 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 OR SUPPLY OF: subcutaneous medroxyprogesterone acetate (MPA) injection for contraception

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	Wendy Billsborough	Wendy Billsborough	29/3/2018.
Clinical Director Lead Approval	Dr Ian Fairley		5/4/2018
Directorate Pharmacy Lead Approval	Jill McEnaney	Jill McEnaney	1.5.2018.

PGD Approved by the Area Prescribing Committee

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		8.5.2018
Chief Pharmacist / Deputy Chief Pharmacist	Stuart PARKES		8/5/18.

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 Lead Authorising Prescribing Committee

- 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 and Sexual Health Outreach Clinics
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

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