NHS
Sunderland
Clinical Commissioning Group

This Patient Group Direction (PGD) must only be used by registered nurses/pharmacists 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

for the initiation and continued administration of

Medroxyprogesterone acetate (DMPA) injection 150mg/mL

by registered nurses/pharmacists for contraception

in GP practices in Sunderland

Version number: 1.0

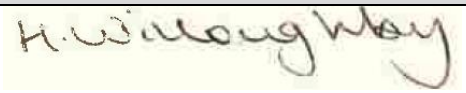
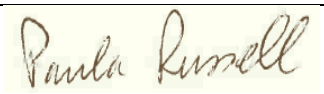
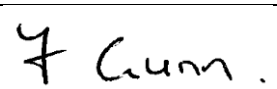
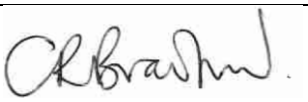
Date PGD comes in to effect:	**March 2016**
Review date:	**January 2018**
Expiry date:	**March 2018**

Change history

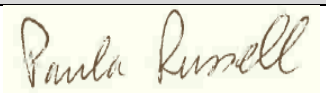
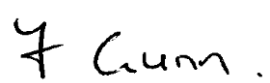
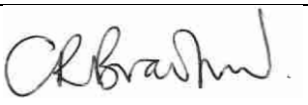
Version number	Change details	Date
V1.0	First approval	March 2016

Valid from: March 2016
Review date: January 2018
Expiry date: March 2018

PGD development

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist Sunderland CCG	**Hannah Willoughby** *(Interface pharmacist)*		March 2016
Medicines optimisation pharmacist Sunderland CCG	**Paula Russell** *(Senior pharmacist)*		March 2016
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		March 2016
Medical director Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		March 2016
Other members of the PGD working group	Not applicable		

PGD authorisation

Name	Job title and organisation	Signature	Date
Medicines optimisation pharmacist Sunderland CCG	**Paula Russell** *(Senior pharmacist)*		March 2016
Practice nurse representative to the executive committee Sunderland CCG	**Florence Gunn** *(Senior nurse)*		March 2016
Medical director Sunderland CCG	**Dr Claire Bradford** *(Senior doctor)*		March 2016
Person signing on behalf of authorising body			

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Valid from: March 2016
Review date: January 2018
Expiry date: March 2018

Training and competency of registered nurses/pharmacists

	Requirements of registered nurses/pharmacists working under the PGD

Qualifications and professional registration	**Healthcare professionals using this PGD must:**
	• **Have a current contract of employment with a GP practice within Sunderland CCG**
	• **Be currently registered with their relevant professional body**
	  o Nurses: the Nursing & Midwifery Council (NMC)
	  o Pharmacists: General Pharmaceutical Council (GPhC)
	• **And at least one of the following:**
	  o Holds a recognised post-registration qualification in contraception/sexual health (an introduction to contraception is not sufficient).
	OR
	  o Significant training and experience in contraception and sexual health. This should be confirmed by documentation on individuals personal file.

Initial training	• Has had training in the use of PGDs • Has had training which enables the nurse/pharmacist to make a clinical assessment in order to establish the contraceptive need and supply the medroxyprogesterone acetate (Depo-Provera®) 150 mg in 1 mL injection according to this PGD. • Has had training which enables the nurse/pharmacist to safely administer medroxyprogesterone acetate (Depo-Provera®) 150 mg in 1 mL injection according to this PGD. • Has undertaken the competency training appropriate to this PGD • Has been assessed and achieved the required standard deemed necessary by the senior medical representative who deems the healthcare professional competent to practice under the PGD. • Is competent in the assessment of the individuals using Fraser guidelines • Has undergone regular training and updates in safeguarding children and vulnerable adults • Has undergone regular updates in basic life support and anaphylaxis
Competency assessment	• Must have demonstrated an appropriate level of competence to the senior medical representative in the practice in contraceptive services.

Ongoing training and competency	• The registered nurse/pharmacist should ensure she/he is aware of any changes to the recommendations for this medication. It is the responsibility of the healthcare professional to keep up-to-date with continuing professional development and take part in audit of clinical records on a regular basis. • Is competent in the assessment of individuals using Fraser guidelines. • Has undergone regular training and updating in safeguarding children and vulnerable adults. • Has undergone regular updating in basic life support and anaphylaxis • Continuous professional development completed as per governing body • Revalidation of professional qualification as dictated by governing body

Clinical condition

Clinical condition to which this PGD applies	To provide long-acting contraception using an injectable progestogen-only contraceptive
Inclusion criteria	• Any individual (menarche to 50 years of age) presenting for long-acting contraception and who has **no** contraindications or exclusion criteria**.**
Exclusion criteria	**Personal characteristics & reproductive history** • Known or suspected pregnancy or risk of pregnancy • Known hypersensitivity to any constituent of the injection • Under 16 years of age and assessed as not competent using Fraser guidelines • History during pregnancy of idiopathic jaundice, severe pruritus, or pemphigoid gestationis • Previous PE, CVD or retinal thrombosis whilst receiving depo-provera • If the woman is at increased risk for osteoporosis, she should consider alternatives to depot medroxyprogesterone acetate **Cardiovascular Disease** • Multiple risk factors for cardiovascular disease e.g. older age, smoking, diabetes, hypertension and obesity • Hypertension with vascular disease • Current and history of ischaemic heart disease • Current and history of stroke/transient ischaemic attack • Diabetes with end organ disease • Diabetes with nephropathy, neuropathy, retinopathy, or other vascular disease. • Vascular disease **Cancers** • Current or past history of genital or breast cancer (unless progestogens are being used in the management of these conditions) • Benign liver tumour or history of liver tumours • Malignant liver tumour (hepatoma) **Gastro-intestinal Conditions** • Severe decompensated cirrhosis **Other conditions** • Systemic Lupus Erythematosus (SLE) with positive or unknown anti-phospholipid antibodies • Systemic Lupus Erythematosus (SLE) with severe thrombocytopenia if starting DMPA • Unexplained vaginal bleeding • Acute porphyria **Drug Interactions** • Check drug history and refer to current BNF for more details and potential drug interactions and ask for advice on management if necessary. All patients taking a medication that interacts significantly

	(indicated with a black dot in the paper version, or shaded red in the online version) with medroxyprogesterone acetate should be excluded. Note: The efficacy of *depot* medroxyprogesterone acetate (DPMA) is <u>not</u> reduced with concurrent use of enzyme-inducing drugs. **Other** • Individual wishes to see a doctor
Cautions (including any relevant action to be taken)	• Severe liver disease and recurrent cholestatic jaundice • If under 13 years of age follow local safeguarding policy • Because of its prolonged action it should never be given without full counselling backed by the patient information leaflet • Ensure emergency drugs and equipment, including adrenaline are available for the treatment of anaphylaxis and emergencies according to local policy • Reduction in bone mineral density and, rarely, osteoporosis and osteoporotic fractures have been reported with medroxyprogesterone acetate. Therefore caution is advised: o in **adolescents**, medroxyprogesterone acetate should be used only when other methods of contraception are inappropriate; o in all women, the benefits of using medroxyprogesterone acetate **beyond 2 years** should be evaluated against the risks; o in women with **risk factors for osteoporosis**, a method of contraception other than medroxyprogesterone acetate should be considered. • Progestogens such as medroxyprogesterone should be used with caution in o Conditions that may worsen with fluid retention e.g. epilepsy, hypertension, migraine, asthma, or cardiac dysfunction, o Patients at risk of thromboembolism (particular caution with high dose). o History of depression. o Diabetes - progestogens can decrease glucose tolerance so patients should be monitored closely.
Arrangements for referral for medical advice	Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse/pharmacist is unsure/uncertain
Action to be taken if patient excluded	• Refer to appropriate doctor / independent nurse prescriber • Discuss/offer alternative contraceptive method • Document all actions taken
Action to be taken if patient declines treatment	• Document refusal in patients notes. • Ensure all actions/decisions are documented. • Ensure patient /carer fully understands reasons for administration and consequences of non-administration of treatment. • Refer to appropriate doctor/independent nurse prescriber where required.

Details of the medicine

<table>
<tr><td>Name, form and strength of medicine</td><td>Medroxyprogesterone acetate (Depo-Provera®) 150 mg in 1 mL injection</td></tr>
<tr><td>Legal category</td><td>Prescription only medicine</td></tr>
<tr><td>Indicate any off-label use (if relevant)</td><td>The Faculty of Sexual and Reproductive Healthcare (FSRH) best practice advice is used in this PGD. This may vary from the SPC.
http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf</td></tr>
<tr><td>Route/method of administration</td><td>Intramuscular
Shake well before administration.
Deep intramuscular injection into the gluteal or deltoid muscle.
Do not massage the site after the injection.</td></tr>
<tr><td>Dose and frequency</td><td>150 mg in 1 mL injection
INITIATION: Faculty of Sexual & Reproductive Healthcare advice on starting progestogen-only injectable contraception:
<table>
<tr><th>Circumstances</th><th>Starting day</th><th>Additional contraceptive protection required?</th><th>Any additional information</th></tr>
<tr><td rowspan="2">Women having menstrual cycles</td><td>≤5 days of menstruation</td><td>No additional precautions required</td><td></td></tr>
<tr><td>Any other time in the menstrual cycle</td><td>Yes (7 days)</td><td></td></tr>
<tr><td>Women who are amenorrhoeic</td><td>Any time if it is reasonably certain she is not pregnant</td><td>Yes (7 days)</td><td></td></tr>
<tr><td rowspan="3">Postpartum[a]</td><td>≤21 days postpartum</td><td>No additional precautions required</td><td>In breastfeeding women, if commencing use before 6 weeks, ideally delay until Day 21</td></tr>
<tr><td>>21 days if menstrual cycles have returned</td><td>Start as for other women having menstrual cycles</td><td>If there has been a risk of pregnancy consider Emergency Contraception and quick starting (see below)</td></tr>
<tr><td>>21 days postpartum if menstrual cycles have not returned</td><td>Yes (7 days)</td><td></td></tr>
<tr><td rowspan="2">Post first- or second-trimester abortion</td><td>Up to and including Day 5[b]</td><td>No additional precautions required</td><td rowspan="2">Hormonal contraceptives can be initiated after the first part of a medical abortion</td></tr>
<tr><td>At any other time if it is reasonably certain she is not pregnant</td><td>Yes (7 days)</td></tr>
</table></td></tr>
</table>

Quick starting after oral emergency contraceptive or other situations where pregnancy cannot be excluded	Ideally bridge to the injectable with an oral contraceptive or start the injectable immediately if criteria for quick starting fulfilled[c]	Additional precautions required after levonorgesterel EC for 7 days or after ulipristal acetate EC for 14 days	Advise a pregnancy test no sooner than 3 weeks after most recent incidence of unprotected sexual intercourse.

a. Prior to 6 weeks postpartum use of DMPA in breastfeeding women is UKMEC (UK Medical Eligibility Criteria for Contraceptive Use) rating 2 (definition: A condition for which the advantages of using the method generally outweigh the theoretical or proven risks).
b. The FSRH advises that women ideally start on the day or day after a first- or second-trimester abortion.
c. See FSRH guidance on Quick Starting Contraception.

EC, emergency contraception; LNG, levonorgestrel; UPA, ulipristal acetate; UPSI, unprotected sexual intercourse.

Faculty of Sexual & Reproductive Healthcare advice when **switching from another contraceptive to progestogen-only injectable contraception**:

Situation	**Starting**	**Additional contraceptive protection required?**	**Additional information**
Switching from combined hormonal contraception (CHC)	Immediately after the last day of active hormone use (i.e. Day 1 of the hormone-free interval)	No additional precautions required	In theory the injectable could be started up to Day 3 of the hormone-free interval without the need for additional precautions as ovulation would not be expected until Day 10
	Week 1 following the hormone-free interval	7 days of additional precautions required. If UPSI has occurred after Day 3 of the hormone-free interval advise restarting the CHC method for at least 7 days	When switching after a 7-day hormone-free interval there are no data to confirm that suppression of ovulation is maintained
	Week 2–3 of pill/ring/patch	No additional precautions required providing the CHC method has been used consistently and correctly for 7 consecutive days before switching	There is evidence to suggest that taking hormonally active pills for seven consecutive days prevents ovulation. Therefore as long as there have been 7 days of CHC use, seven hormone-free

			days can occur without any effect on contraceptive efficacy
Switching from progestogen-only pill (POP) or levonorgestrel intrauterine system (LNG-IUS)	Any time	Yes for 7 days or continue method for 7 days	The continuing method provides contraceptive cover while the effects of the injectable are established
Switching from progestogen-only implant	≤3 years since implant insertion	No additional precautions required	
	>3 years since implant insertion	Yes (7 days)	If there has been a risk of pregnancy consider the need for EC and a pregnancy test no sooner than 3 weeks after the most recent incidence of UPSI
Switching from barrier methods	Can be started immediately if the previous method was used consistently and correctly	Yes (7 days) unless the injectable is given within Day 1-5 of the menstrual cycle	
Switching from copper intrauterine device (Cu-IUD)	Day 1–5 of menstrual cycle	No additional precautions required	
	Any other time	Yes for 7 days or continue method for 7 days	The continuing method provides contraceptive cover while the effects of the injectable are established

CHC, combined hormonal contraception; EC, emergency contraception; UPSI, unprotected sexual intercourse.

Quick Start method:

- DMPA can be started at *any time* as 'quick start' if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 7 days after starting.

- If quick start' after levonorgestrel EC, 7 days of additional precautions are needed.
- If 'quick start' after ulipristal acetate EC, 14 days of additional precautions are needed.

ON- GOING ADMINISTRATION

Dosing Interval:

	• **DMPA should be repeated between 10 and 12 weeks after the last injection.** • A repeat injection can be given **up to 14** weeks after the previous dose with no additional contraceptive precautions required. • If the individual presents **after 14 weeks** and has had no unprotected sexual intercourse (UPSI) since week 14, DMPA may be given with additional contraceptive precautions for a further 7 days. • **If the timing of a woman's previous DMPA injection is unknown** o the injection can be given if it is reasonably certain that the woman is not pregnant. Additional contraceptive precautions are needed for the next 7 days. o If there is a risk of pregnancy, the woman is excluded from the PGD. o A pregnancy test should be advised no sooner than 3 weeks after the most recent episode of UPSI.
Quantity to be administered and/or supplied	Single 1mL dose
Maximum or minimum treatment period	Dosing Interval: o Minimum ten weeks o Maximum fourteen weeks For as long as the individual requires DMPA and has no contraindications to use of DMPA. Long-term users should be reviewed at least every 2 years by a prescriber. In deciding whether continued use is appropriate the prescriber should assess risks, benefits and user preferences.
Adverse effects	Refer to the current SPC for the product and the current British National Formulary (BNF) for information **Common** • Dermatologic: injection site reaction (5%) • Endocrine metabolic: weight gain (IM route, 37.7%) • Gastrointestinal: abdominal pain (up to 11.2%) • Neurologic: dizziness (up to 5.6%), headache (9% to 16.5%) • Psychiatric: feeling nervous (10.8%) • Other: fatigue (1% to less than 5%) • Reproductive: amenorrhea (up to 68%), disorder of menstruation, menstrual spotting (7%), reduced libido (5.5%) Women should be informed that there could be a delay of up to 1 year in the return of fertility after stopping the use of injectable contraceptives. As there is wide inter-individual variation in return of fertility, women who do not wish to conceive should be advised to start another contraceptive method before or at the time of the next scheduled injection. **Serious** • Immunologic: anaphylaxis • Musculoskeletal: decreased bone mineral density, fracture of bone.

	This is of particular concern for individuals who have not yet attained peak bone mass (i.e. women aged under 18 years). The risk of this should be discussed with the individual, and should be reassessed every two years. In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via freephone 0800 731 6789 or online at www.yellowcard.mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Records to be kept	• The nurse/pharmacist must ensure the following is documented in the individual's clinical record: • Individual's: name, address and date of birth, attendance date, past and present drug, medical and family history • Any known allergy • Usual GP and their contact details • Initial examination - to include body mass index (BMI) and blood pressure recording; thereafter in accordance with local policy • Drug: date of last administration, date of current administration, name, dose, site of administration, batch number and expiry date • "Supplied and administered under PGD" • The consent of the individual or refusal • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record action taken. Include action taken regarding safeguarding. • Any advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the product licence • If individual is under16 years of age document competency using Fraser guidelines • Record follow up arrangements • Signature and designation of nurse/pharmacist who administered the medication (if paper record).

Patient information

Information to be given to patient or carer	• Provide manufacturer's patient information leaflet (PIL) and discuss it in full. Provide a copy of the FPA leaflet on injectable contraception • Explain mode of action, side effects, and benefits and when to return for repeat injection. • Advise not to massage the site after the injection • Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken • 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 contact details of the service
Follow-up advice to be given to patient or carer	• Ensure individual has the contact details of the clinic/GP practice • Individual to return to clinic/GP practice if she has any concerns • Advise individual what to do if has concerns out of hours Return to clinic in 10 to 12 weeks for review and repeat injection. • A review will be undertaken every 2 years.

Appendices

Appendix A Key references

1. British National Formulary BNF February 2015
2. Summary of Product Characteristics www.medicines.org.uk
3. Faculty of Sexual & Reproductive Healthcare Clinical Guidance. Progestogen-only Injectable Contraception Clinical Effectiveness Unit. December 2014 (Updated March 2015) http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf
4. Nursing and Midwifery Council (NMC) (2008) Standards for medicine management
5. National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidance (MPG2)
6. Drugdex by Micromedex solutions, Truven Healthcare solutions
7. UKMEC for contraceptive use 2009

Appendix B Health professionals' agreement to practise

I have read and understood the Patient Group Direction and agree to supply and/or administer Medrogyprogesterone acetate (Depo-Provera) 150mg injection only in accordance with this PGD.

Name of registered nurse/pharmacist	Signature	Senior representative authorising nurse/pharmacist	Date