
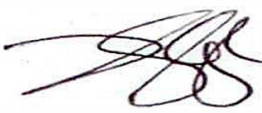


**Patient Group Direction For The Initial And Repeat Administration Of  
 Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By  
 Approved Healthcare Professionals Working Within NHS Grampian,  
 Highland, Orkney, Shetland, Tayside and Western Isles**

<b>Lead Author:</b> Adapted from the SPS/FSRH National PGD Template by the Medicines Management Specialist Nurse NHSG	<b>Consultation Group:</b> See relevant page in the PGD	<b>Approver:</b> NoS PGD Group  <b>Authorisation:</b> NHS Grampian
--	---	--

<b>Signature:</b>  		<b>Signature:</b>  
--	--	--

<b>NoS Identifier:</b> NoS/PGD/SC- DMPA/MGPG1356	<b>Review Date:</b> May 2025  <b>Expiry Date:</b> May 2026	<b>Date Approved:</b> May 2023
--	--	-----------------------------------

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have  
 authorised this Patient Group Direction to help individuals by providing them with  
 more convenient access to an efficient and clearly defined service within the NHS  
 Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are  
 completed.

**Uncontrolled when printed**  
  
**Version 2**

**Revision History:**

<b>Reference and approval date of PGD that has been adapted and/or superseded</b>	PGD supersedes NoS/PGD/SC_DMPA/MGPG1142, Version 1	
<b>Date of change</b>	<b>Summary of Changes</b>	<b>Section heading</b>
December 2022	2 yearly review on new PGD template.	
December 2022	Current metabolic bone disease added as per current SmPC.	Exclusion criteria
December 2022	Insomnia, anxiety and affective disorder as well as back pain and pain in extremity added.	Identifying and managing possible adverse reactions
December 2022	Statement, once opened: use immediately, discard any unused portion added.	Additional information
December 2022	References updated.	References
December 2022	Added statements regarding child protection.	Inclusion criteria
December 2022	Statements regarding consent and safeguarding removed as now covered in new statements in inclusion criteria.	Precautions and special warning
March 2023	Statement added about gender based violence and welfare.	Precautions and special warnings
March 2023	Healthy bone advice and hyperlink added.	Advice (Verbal)
March 2023	Added Acute porphyria.	Exclusion criteria

**NoS Identifier:** NoS/PGD/SC\_DMPA/MGPG1356  
**Keyword(s):** PGD Patient Group Direction contraception contraceptive initial repeat Sayana Press® Medroxyprogesterone Acetate Injection Subcutaneous DMPA

**Policy Statement:** It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	December 2022
	Completed:	March 2023
	Approved:	May 2023 (published – June 2023)
	Amended and re-authorised:	


## Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.


PGD Developed/Reviewed by;

<p><b>Medical practitioner</b></p>	<p><b>Name:</b> Dr Heike Gleser  <b>Health Board:</b> NHST  <b>Title:</b> Consultant Sexual and Reproductive Health  <b>Contact email:</b> <a href="mailto:heike.gleser@nhs.scot">heike.gleser@nhs.scot</a>  <b>Signature:</b>  .....  <b>Date:</b> 09/06/2023</p>
<p><b>Senior representative of the professional group who will provide care under the direction</b></p>	<p><b>Name:</b> Julia Penn  <b>Health Board:</b> NHSG  <b>Title:</b> Sexual Health Nurse Manager  <b>Contact email:</b> <a href="mailto:julia.penn@nhs.scot">julia.penn@nhs.scot</a>  <b>Signature:</b>  .....  <b>Date:</b> 25/05/2023</p>
<p><b>Lead author</b></p>	<p><b>Name:</b> Jodie Allan  <b>Health Board:</b> NHSG  <b>Title :</b> Medicines Management Specialist Nurse  <b>Contact email:</b> <a href="mailto:jodie.allan@nhs.scot">jodie.allan@nhs.scot</a>  <b>Signature:</b>  .....  <b>Date:</b> 23/05/2023</p>
<p><b>Pharmacist</b></p>	<p><b>Name:</b> Findlay Hickey  <b>Health Board:</b> NHSH  <b>Title :</b> Pharmacist  <b>Contact email:</b> <a href="mailto:findlay.hickey2@nhs.scot">findlay.hickey2@nhs.scot</a>  <b>Signature:</b>  .....  <b>Date:</b> 24/05/2023</p>

**Approved for use within NoS Boards by;**

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		23/05/2023

**Authorised and executively signed for use within NoS Boards by;**

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		12/06/2023

**Management and Monitoring of Patient Group Direction**

**PGD Consultative Group**

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

<b>Name:</b>	<b>Title:</b>
Jodie Allan	<b>Lead Author:</b> Medicines Management Specialist Nurse NHSG
Findlay Hickey	<b>Pharmacist:</b> NHSH
Dr Heike Gleser	<b>Medical Practitioner:</b> Consultant Sexual and Reproductive Health NHST
Julia Penn	<b>Senior Representative:</b> Sexual Health Nurse Manager NHSG
Sara Beveridge	Clinical Nurse Specialist NHST
Kimberly MacInnes	Service Manager/Lead Nurse Sexual Health Service NHSH
Dr Diana Reed	Consultant Sexual and Reproductive Health NHSG
Deborah Syme	Team Leader The Corner NHST

**Patient Group Direction For The Initial And Repeat Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles**

**Clinical indication to which this PGD applies**

<p><b>Definition of situation/ Condition</b></p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals to administer subcutaneous medroxyprogesterone acetate (SC-DMPA) injection to all individuals who wish to commence the use of SC-DMPA as their method of contraception.</p> <p>SC-DMPA provides safe and effective contraception, however careful assessment is needed to identify the individuals for whom it is a suitable option. Explanation to allow informed choice and correct use of this method of contraception is essential.</p> <p>This PGD should be used in conjunction with individual Board protocols and the recommendations in the current British National Formulary (<a href="#">BNF</a>), the individual Summary of Product Characteristics (<a href="#">SmPC</a>), and the relevant The Faculty of Sexual and Reproductive Healthcare (<a href="#">FSRH</a>) Clinical Guidance.</p>
<p><b>Inclusion criteria</b></p>	<p>Individuals aged from 13 years (with established menstrual cycles) up to and including 50 years of age who:</p> <ul style="list-style-type: none"> <li>• Have no absolute or relative contra-indications to its use.</li> <li>• Choose SC-DMPA injection as their method of contraception.</li> <li>• Wish to continue with SC-DMPA injection as their method of contraception and have no absolute or relative contraindications to its use.</li> <li>• Wish to switch from IM-DMPA (intramuscular) to SC-DMPA as their method of contraception and have no absolute or relative contraindications to its use.</li> </ul> <p>Prior to the administration of SC-DMPA injection, valid consent to receiving treatment under this PGD must be obtained.</p> <p>Consent must be in line with current individual NHS Boards' consent policy.</p> <p><b>Note:</b> The healthcare professional must use their professional judgement to consider and where appropriate, act on any or child protection and wellbeing issues coming to their attention as a result of providing the service. This should be in line with local child protection procedures and any national or local guidance on under 16s sexual activity.</p>

	<p>An individual under 16 years of age may give consent for the administration of the SC-DMPA, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the administration, administration should proceed, if the healthcare professional deems the individual to have the legal capacity to consent. The Age of Legal Capacity (Scotland) Act 1991, Section 2 (4) (commonly referred to as Fraser guideline) states that ‘a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment’.</p> <p>If under 13 years of age this PGD cannot be used and the healthcare professional should speak to the local Child Protection lead and follow the local child protection policy.</p>
<p><b>Exclusion criteria</b></p>	<p>This PGD is not suitable for individuals with conditions in UK Medical Eligibility Criteria categories 3 and 4. See <a href="#">UKMEC for contraceptive use</a> for guidance.</p> <p>Under this PGD, SC-DMPA should <b>not</b> be administered to individuals with the following characteristics:</p> <ul style="list-style-type: none"> <li>• Where there is no valid consent.</li> <li>• Individuals under 13 years of age (the healthcare professional should speak to the local Child Protection lead and follow the local child protection policy).</li> <li>• Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991 (commonly referred to as Fraser competency).</li> <li>• Individuals 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines.</li> <li>• Aged 51 years or older.</li> </ul> <p><b>Medical History</b></p> <ul style="list-style-type: none"> <li>• Known or suspected pregnancy.</li> <li>• Planning pregnancy within the next year.</li> <li>• Unexplained vaginal bleeding suspicious of a serious medical condition, before evaluation.</li> <li>• Current metabolic bone disease.</li> <li>• Acute porphyria.</li> </ul>

	<p><b>Cardiovascular Disease</b></p> <ul style="list-style-type: none"> <li>• Current or past history of ischaemic heart disease, vascular disease, stroke or first transient ischaemic attack.</li> <li>• Individuals with multiple risk factors for cardio-vascular disease (such as smoking, diabetes, hypertension, obesity and dyslipidaemias).</li> <li>• Hypertension with vascular disease.</li> </ul> <p><b>Tumours or Cancers</b></p> <ul style="list-style-type: none"> <li>• Current or past malignancy of the breast or hormone dependant cancer.</li> <li>• Current or past benign liver tumour (hepatocellular adenoma).</li> <li>• Malignant liver tumour (hepatocellular carcinoma).</li> </ul> <p><b>Gastro-intestinal conditions</b></p> <ul style="list-style-type: none"> <li>• Severe decompensated cirrhosis.</li> </ul> <p><b>Currently prescribed interacting medicines</b> – see current British National Formulary (<a href="#">BNF</a>) or individual product <a href="#">SmPC</a>.</p> <p>Individuals for whom no valid consent has been received.</p>
<p><b>Precautions and special warnings</b></p>	<ul style="list-style-type: none"> <li>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.</li> <li>• If the presenting individual is under 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD).</li> <li>• Any gender based violence, child protection and welfare issues or adult protection concerns should be referred through the appropriate channels.</li> <li>• Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.</li> <li>• Individuals aged under 18 years should not use SC-DMPA first line for contraception because of its effect on bone mineral density. SC-DMPA may be considered if all alternative contraceptive options are unsuitable or unacceptable.</li> <li>• The individuals medical and lifestyle risks for osteopenia/osteoporosis and the benefits and potential risks of SC-DMPA must be discussed and documented prior to its initial administration, and every 2 years or sooner if there is a relevant clinical change.</li> </ul>



	<ul style="list-style-type: none"> <li>• Other methods of contraception should be considered first where there is significant risk. SC-DMPA may be considered if all alternative contraceptive options are unsuitable or unacceptable. Significant risk factors for osteoporosis include: <ul style="list-style-type: none"> <li>○ Alcohol addiction</li> <li>○ Smoking or vaping</li> <li>○ Chronic use of drugs that can reduce bone mass, e.g. anticonvulsants or corticosteroids</li> <li>○ Low body mass index (&lt;18.5) or eating disorder, e.g. anorexia nervosa or bulimia</li> <li>○ Previous low trauma fracture</li> <li>○ Family history of osteoporosis</li> </ul> </li> <li>• If an individual is known to be taking a medication which is known to be harmful to pregnancy, a highly effective form of contraception is recommended, for example, IUD/IUS or the subdermal implant. If these methods are unacceptable or unsuitable and SC-DMPA is chosen, then an additional barrier method of contraception is advised. See <a href="#">FSRH advice</a>.</li> <li>• SC-DMPA does not affect breast feeding. The FSRH supports the use of injectable progestogens in those breast feeding as there is no evidence of any effect on lactation or infant growth or development. See FSRH Clinical Guidance <a href="#">Contraception After Pregnancy</a>.</li> </ul>
<p><b>Action if excluded from treatment</b></p>	<p>Medical advice must be sought – refer to relevant medical practitioner (GP or Sexual and Reproductive Health Service) if appropriate and/or provide them with information about further options.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records.</p>
<p><b>Action if treatment is declined</b></p>	<p>Medical advice must be sought – refer to relevant medical practitioner if appropriate (GP or Sexual and Reproductive Health Service) and provide them with information about further options.</p> <p>Document that the administration was declined, the reason and advice given in appropriate clinical records.</p>

## Description of treatment available under the PGD

<b>Name form and strength of medicine</b>	Medroxyprogesterone acetate (SC-DMPA) (e.g. Sayana Press®) 104mg in 0.65mL injection.
<b>Legal status</b>	SC-DMPA is a Prescription-only Medicine (POM).  <b>Note:</b> This PGD does not restrict which brands can be supplied – local formularies/restrictions should be referred to.
<b>Is the use outwith the SmPC?</b>	<p>Best practice advice is given by the FSRH and is used for guidance in this PGD and may vary from the SmPC.</p> <p>This PGD specifically includes inclusion criteria and dosage regimens which are outside the market authorisation for many of the available products but which are included within FSRH guidance:</p> <ul style="list-style-type: none"> <li>• Can be administered between 10 to 14 weeks + 0 days. However, administration at under 13 weeks from the last administration should not be routinely or consistently undertaken and 13 week intervals should be advised.</li> <li>• Refer to FSRH guidance for administration after 14 weeks + 0 days.</li> <li>• Administration after five days postpartum if not breast feeding/before six weeks postpartum if breast feeding. FSRH guidance supports the use of SC-DMPA any time after childbirth for both breastfeeding and non-breastfeeding individuals.</li> </ul> <p>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual that the medicine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Dosage/Maximum total dose</b>	Single administration of one injection (104mg/0.65mL).

<p><b>Frequency of dose/Duration of treatment</b></p>	<ul style="list-style-type: none"> <li>• Single pre-filled injector (104mg/0.65mL) on day 1 to 5 of the menstrual cycle with no need for additional protection, for as long as individual requires SC-DMPA and has no contraindications to its use.</li> <li>• SC-DMPA can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional precautions are then required for 7 days after starting.</li> <li>• Easier reversible bridging methods (POP, CHC, condoms) should be offered as first line but declined before offering to quick start SC-DMPA when there is a pregnancy risk and a pregnancy test is negative. However, when starting or restarting SC-DMPA as quick start after levonorgestrel emergency contraception, additional barrier contraception is required for 7 days and a follow up pregnancy test at 21 days is required. The pregnancy test should be offered in the service, especially for patients under 18 and vulnerable adults.</li> <li>• In line with FSRH guidance individuals should delay starting or restarting hormonal contraception for 5 days following use of ulipristal acetate for emergency contraception. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised for a further 7 days and a follow up pregnancy test at 21 days is required. The pregnancy test should be offered in the service, especially for patients under 18 and vulnerable adults.</li> <li>• SC-DMPA dose should be repeated 13 weeks after the last injection.</li> <li>• If required, a repeat injection can be given up to 14 weeks + 0 days after the previous dose with no additional contraceptive precautions.</li> <li>• If required, on an occasional basis, SC-DMPA injection may be repeated as early as 10 weeks after the last injection.</li> <li>• If the interval from the preceding injection is greater than 14 weeks + 0 days and unprotected sexual intercourse (UPSI) has occurred, the injection may be administered. The professional administering the injection should <a href="#">refer to FSRH current guidelines</a> for advice on the need for pregnancy testing, emergency contraception, extra precaution and pregnancy testing.</li> <li>• For guidance on changing from one contraceptive method to another and when to start after an abortion or postpartum, refer to the FSRH guidelines.</li> <li>• If no significant lifestyle and/or medical risk factors for osteoporosis are identified then it is safe to continue SC-DMPA for longer than 2 years.</li> </ul>
---	--

<b>Maximum or minimum treatment period</b>	<p>For as long as individual requires SC-DMPA and has no contraindications to its use.</p> <p><b>Note:</b> In individuals of all ages, careful re-evaluation of the risks and benefits of treatment should be carried out in those who wish to continue use every 2 years. Refer to “Precautions and Special Warnings”.</p>
<b>Route/Method of administration</b>	<p>Subcutaneous injection (SC)</p> <p><b>Advice for administration:</b></p> <ul style="list-style-type: none"> <li>• Follow manufacturer’s guidance for administration.</li> <li>• Shake the injector vigorously before administration for at least 30 seconds.</li> <li>• Inject into the upper anterior thigh or the anterior abdomen, avoiding bony areas or the umbilicus and areas of inflamed or broken skin.</li> <li>• Ensure that the full injection is given. The medication should be injected slowly over approximately 5 to 7 seconds with the needle pointing downwards.</li> <li>• Do not massage the site after the administration of the injection.</li> </ul> <p><b>Note:</b> When administering SC-DMPA the healthcare professional must only use a pre-filled injector from stock under this PGD and must not use any pre-filled injector which has been supplied by the individual.</p>
<b>Quantity to be administered</b>	<p>A single dose is to be administered per episode of care.</p>
<b>Storage requirements</b>	<p>Do not refrigerate or freeze.</p>
<b>Additional Information</b>	<p>Once opened: use immediately, discard any unused portion.</p>
<b>Follow-up (if applicable)</b>	<p>Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the medicine first. If necessary a doctor or the individual’s GP should be contacted for advice.</p> <p>Review in 13 weeks or earlier if problems arise.</p>

**Advice (Verbal)**

- Advise individual on mode of action, side effects, benefits of medicine and of the possible side effects and the management of side effects.
- Advise individual what to expect and what to do for minor and major reactions. Individuals should be informed about the altered bleeding patterns that usually occur with the use of SC-DMPA injectable contraceptive, e.g. amenorrhoea, infrequent bleeding, spotting and prolonged bleeding. Also discuss delay of fertility for up to a year when stopping, and possible weight gain due to increased appetite.
- It may take up to 12 months (mean 9 months) for fertility to return after injection. There is no permanent effect on fertility. This must be discussed and documented prior to initial administration of SC-DMPA.
- SC-DMPA injection cannot be reversed if side effects develop. This must be clearly explained before administration of the injection.
- If patients develop a serious or persisting injection site reaction on their skin (redness, itchiness, swelling, scarring or a dimple) they should seek medical advice before receiving (or self-administering) a further SC-DMPA injection.
- Individuals should be informed that SC-DMPA injectable contraceptive use is associated with a small loss of bone mineral density, which is usually recovered after discontinuation. For this reason they should be informed that use of this method may be time limited, and review will take place after 2 years of use.
- Healthy bone advice (a well-balanced, calcium rich diet, regular weight-bearing exercise, get outdoors and avoid excessive alcohol and smoking)
  - [Bone Health for All Advice](#)
- Give advice about adequate intake of calcium and Vitamin D, whether from the diet or from supplements, it is important for bone health in women of all ages.
- Repeat injections should be planned at appropriate intervals as discussed in “Frequency of dose/Duration of treatment”.
- If attending a GP or other healthcare professional for any illness they should make them aware that they are using SC-DMPA for contraception.
- SC-DMPA can be self-administered. Discuss this option with every patient. Teach self-administration or refer to a healthcare professional who can teach this if this is a suitable option and the patient is interested.
- If serious adverse or persistent effects occur, the individual/parent/carer should be advised to contact their GP/Accident and Emergency department/NHS24.

	<ul style="list-style-type: none"> <li>Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <a href="#">Yellow Card reporting scheme</a>.</li> </ul> <p><b>Note:</b> Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections (STIs). Ensure the individual has contact details of local service/sexual health services.</p>
<b>Advice (Written)</b>	<p>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p>
<b>Identifying and managing possible adverse reactions</b>	<p>The following possible adverse effects are commonly or very commonly (<math>\geq 1/100</math>) reported with SC-DMPA (but may not reflect all reported adverse effects):</p> <ul style="list-style-type: none"> <li>Injection site reactions including possible irreversible skin dimpling or indentation at injection site (approximately 6%).</li> <li>Weight change (SC-DMPA use appears to be associated with some weight gain in some individuals, particularly individual aged under 18 with a BMI <math>\geq 30</math> kg/m<sup>2</sup>).</li> <li>Fluid retention.</li> <li>Headache, dizziness.</li> <li>Alopecia, rash, acne.</li> <li>Changes in mood or depression.</li> <li>Insomnia, anxiety and affective disorder.</li> <li>Back pain and pain in extremity.</li> <li>Loss of libido.</li> <li>Breast tenderness or abnormalities.</li> <li>Vaginal discharge.</li> <li>Disturbance of bleeding patterns.</li> <li>Abdominal discomfort or distension, nausea.</li> <li>Association with a small loss of bone mineral density which is recovered after discontinuation of the injection.</li> <li>There is a possible weak association between current use of SC-DMPA and breast cancer and a weak association between cervical cancer and use of SC-DMPA - any increased risk is likely to be small and reduce with time after stopping.</li> </ul> <p><b>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</b></p> <p><b>BNF/BNFC:</b>  <a href="#">BNF British National Formulary - NICE</a>  <a href="#">BNF for Children British National Formulary - NICE</a></p>

	<p><b>SmPC/PIL/Risk Minimisation Material:</b>  <a href="#">Home - electronic medicines compendium (emc)</a>  <a href="#">MHRA Products   Home</a>  <a href="#">RMM Directory - (emc)</a></p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Document in accordance with locally agreed procedures in the individual's record.</p> <p>Report any suspected adverse reactions using the Yellow Card System. <a href="#">Yellow Card Scheme - MHRA.</a></p>
<p><b>Facilities and supplies required</b></p>	<p>The following are to be available at sites where the medicine is to be administered:</p> <ul style="list-style-type: none"> <li>• Appropriate storage facilities.</li> <li>• An acceptable level of privacy to respect individual's right to confidentiality and safety.</li> <li>• Basic airway resuscitation equipment (e.g. bag valve mask).</li> <li>• Immediate access to epinephrine (adrenaline) 1 in 1000 injection.</li> <li>• Access to a working telephone.</li> <li>• Another competent adult, who can summon urgent emergency support if required should ideally be present.</li> <li>• Access to medical support (this may be via the telephone).</li> <li>• Approved equipment for the disposal of used materials.</li> <li>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel.</li> <li>• Condoms.</li> <li>• A copy of this current PGD in print or electronically.</li> </ul>

**Characteristics of staff authorised to administer medicine(s) under PGD**

<p><b>Professional qualifications</b></p>	<p>Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC).</p>
<p><b>Specialist competencies</b></p>	<p><b>Approved by the organisation as:</b></p> <ul style="list-style-type: none"> <li>• Contraception Qualification (this includes; Family Planning Certificate, and/or post-graduate studies in Contraception and Sexual and Reproductive Health) and have evidence of continuing professional development .</li> <li>• Understanding of child protection and vulnerable adult issues and training undertaken as per individual Board requirements.</li> </ul>

	<ul style="list-style-type: none"> <li>• Competent to assess the individual’s capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent.</li> <li>• Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual.</li> <li>• Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD.</li> <li>• Competent to undertake administration of the medicine.</li> <li>• Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.</li> <li>• Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.</li> </ul>
<p><b>Ongoing training and competency</b></p>	<p><b>All professionals working under this PGD must:</b></p> <ul style="list-style-type: none"> <li>• Have undertaken NoS PGD module training on <a href="#">TURAS Learn</a>.</li> <li>• Have attended basic life support training either face to face or online and updated in-line with individual Board requirements.</li> <li>• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with individual Board requirements.</li> <li>• Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct. <b>Note:</b> All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. Any training needs re identified should be discussed with those responsible for authorisation to act under the PGD.</li> <li>• Have knowledge and familiarity of the following; <ul style="list-style-type: none"> <li>○ <a href="#">SmPC</a> for the medicine(s) to be administered in accordance with this PGD.</li> </ul> </li> </ul>
<p><b>Responsibilities of professional manager(s)</b></p>	<p><b>Professional manager(s) will be responsible for;</b></p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.</p>



## Documentation

<p><b>Authorisation of administration</b></p>	<p>Nurses working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.</p> <p>Midwives working within NHS Highland <b>only</b> can be authorised to administer the medicine specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (<a href="#">Appendix 1</a>).</p> <p>A Certificate of Authorisation (<a href="#">Appendix 2</a>) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.</p>
<p><b>Record of administration</b></p>	<p>An electronic or paper record must be completed to allow audit of practice.</p> <p>An electronic/HEPMA record of the screening and subsequent administration, or not, of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.</p> <p>If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum:</p> <ul style="list-style-type: none"> <li>• Date and time of administration.</li> <li>• Individual's name and CHI.</li> <li>• Exclusion criteria, record why the medicine was not administered (if applicable).</li> <li>• Record that valid consent to treatment under this PGD was obtained.</li> <li>• The name, dose, form, route (batch number, expiry date and anatomical site, where appropriate, for injectable medicines) of the medicine(s) administered.</li> <li>• Advice given, including advice given if excluded or declined treatment under this PGD.</li> <li>• Signature and name in capital letters of the healthcare professional who administered the medicine, and who undertook the assessment of the individual's clinical suitability for the administration/supply of the medicine.</li> <li>• Record of any adverse effects and the actions taken (advise individual's GP/relevant medical practitioner).</li> </ul>

	<p>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:</p> <ul style="list-style-type: none"> <li>• NaSH – Sexual Health Electronic Patient Record.</li> <li>• BadgerNet – Digital Maternity Notes.</li> <li>• Individual’s GP records if appropriate.</li> <li>• HEPMA.</li> <li>• Individual service specific systems.</li> </ul> <p>Local policy should be followed with respect to sharing information with the individual’s General Practitioner.</p> <p>All records should be clear, legible and contemporaneous and in an easily retrievable format.</p>
<b>Audit</b>	<p>All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</p>
<b>References</b>	<p>Electronic Medicines Compendium  <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> Sayana Press® Date of revision of text March 2020, accessed 07/12/2022.</p> <p>British National Formulary <a href="https://www.bnf.org/products/bnf-online/">https://www.bnf.org/products/bnf-online/</a> accessed. 07/12/2022.</p> <p>The Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: <a href="#">Progestogen-only injectable</a>, December 2014, amended October 2020. (Accessed 07/12/2022).</p> <p>FRSH Clinical Guideline: <a href="#">Quick Starting Contraception</a>, April 2017. (Accessed 07/12/2022).</p> <p>FSRH Guidance <a href="#">Switching or Starting Methods of Contraception</a> (Updated March 2021) (Access for FSRH members only)</p> <p>The Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: <a href="#">UK medical eligibility criteria for contraceptive use</a>, April 2016, <b>amended September 2019</b>. (Accessed 07/12/2022).</p> <p>The Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: <a href="#">Contraception After Pregnancy</a>, October 2020. (Accessed 07/12/22).</p>



## Appendix 1

### Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: \_\_\_\_\_ (Insert name)

Working within: \_\_\_\_\_ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

#### **Patient Group Direction For The Initial And Repeat Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles**

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

**Signed:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Profession:** \_\_\_\_\_

**Professional Registration number/PIN:** \_\_\_\_\_

**Appendix 2**

**Healthcare Professionals Authorisation to Administer Medicine(s)  
 Under Patient Group Direction**

**The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

**The Senior Nurse/Professional** who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

**The Healthcare Professional** that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

**Patient Group Direction For The Initial And Repeat Administration Of  
 Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By  
 Approved Healthcare Professionals Working Within NHS Grampian,  
 Highland, Orkney, Shetland, Tayside and Western Isles**

**Local clinical area(s) where the listed healthcare professionals will operate under this PGD:**

<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>

**Patient Group Direction For The Initial And Repeat Administration Of Subcutaneous Medroxyprogesterone Acetate (SC-DMPA) Injection By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles**

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date