University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of

LEVONORGESTREL INTRAUTERINE SYSTEM (Mirena®)

By Clinical Nurse Specialist in colposcopy/hysteroscopy clinic at Royal Derby Hospital

Documentation details

Reference no:	UHDB155
Version no:	1
Valid from:	11/05/2022
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Expiry date:	10/05/2025

Change history

Version number	Change details	Date
V1	New template	23/3/22

Glossary

Abbreviation	Definition
BSSCP	British Society for Colposcopy and Cervical Pathology
IUS	Intrauterine System
FRSH	Faculty of Sexual & Reproductive Healthcare

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Mr O Tamizian	Lead Colposcopist
Miss S Kolhe	Lead Hysteroscopist
Mrs G Lowe	Lead Nurse Colposcopist
Mr D Casayuran	Nurse Hysteroscopist
S Dumbleton	Women and Children's Lead Pharmacist

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A		

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Colposcopy and Hysteroscopy Department within Gynaecology Out Patients department at Royal Derby Hospital
Limitations to authorisation
The professionals to which this protocol applies are the clinical nurse specialist(s) in colposcopy and hysteroscopy.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	**Signed copy held by Pharmacy**	**11/05/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Women's and Children's Lead Pharmacist	Susi Dumbleton	**Signed copy held by Pharmacy**	**29/03/2022**
Lead Colposcopist	Onnig Tamizian	**Signed copy held by Pharmacy**	**24/03/2022**
Lead Hysteroscopist	Shilpa Kolhe	**Signed copy held by Pharmacy**	**03/05/2022**
Clinical nurse Specialist in colposcopy	Gaynor Lowe	**Signed copy held by Pharmacy**	**25/03/2022**
Clinical nurse Specialist in hysteroscopy	Dennis Casayuran	**Signed copy held by Pharmacy**	**24/03/2022**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered nurse with a current NMC registration
Initial training	• Completion of all Essential-to-role training as outlined in the UHDB PGD policy. • Individual has read and understood full content of this PGD and signed authorisation (section 7) • Completion of Medicines Management Drug Assessment • Trained according to the British Society for Colposcopy and Cervical Pathology guidelines or has completed nurse hysteroscopist training. • Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the protocol. • It is the responsibility of the individual nurse to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice. • Has undertaken local training based on the use of Levonorgestrel Intrauterine system PGD. • Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the last year. • Has undertaken local anaesthetic training as applied to IUS insertions. • Has undertaken training in bimanual pelvic examination; to be completed before attempting training to fit IUS.
Competency assessment	Approved drug assessment. Competency Based Assessment. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	• Annual Medicines Safety Training (essential to role). • Individual staff members must have undertaken sufficient insertions and removals each year to maintain competence. • Review/repeat initial training above when this PGD is revisedIt is the responsibility of the individual registered nurse to remain updated, with evidence of continued professional development in relation to colposcopy and hysteroscopy services including annual mandatory training in CPR/life support/anaphylaxis competences, with evidence of updates as required.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Idiopathic menorrhagia. Levonorgestrel Intrauterine System (Mirena®) may be particularly useful in women with idiopathic menorrhagia requiring (reversible) contraception • Protection from endometrial hyperplasia or during oestrogen replacement therapy • Contraception
Criteria for inclusion	• Patients attending out-patient hysteroscopy clinic with heavy menstrual bleeding • Patients requiring contraception who prefer an intra-uterine system (note the FSRH supports extended use of a Mirena® 52 mg levonorgestrel intrauterine system (LNG-IUS) for contraception until the age of 55 if inserted at age 45 or over, provided it is not being used as the progestogen replacement therapy (HRT) for endometrial protection. • Patients with endometrial hyperplasia following MDT direction • Protection from endometrial hyperplasia during oestrogen replacement therapy.
Criteria for exclusion	• Patients who refuse treatment under PGD • Confirmed or suspected hormone dependent tumours including breast cancer • Known or suspected pregnancy (perform pregnancy test if required) • Current or recurrent pelvic inflammatory disease • Cervicitis • Current genital infection • Postpartum endometritis, infected abortion during the past three months • Conditions associated with increased susceptibility to infections • Cervical dysplasia • Uterine or cervical malignancy • Undiagnosed abnormal genital bleeding • Congenital or acquired abnormality of the uterus including fibroids if they distort the uterine cavity • Liver tumour or other acute severe liver disease • Acute malignancies affecting the blood or leukaemia except when in remission • Recent trophoblastic disease while hCG levels remain elevated • Hypersensitivity to the active substance or any of the excipients

Cautions including any relevant action to be taken	• Assess for risk of STIs particularly Chlamydia and for gonorrhoea depending on history and other predisposing factors e.g. under 25 years of age, multiple sex partners, new partner • Take Chlamydia swabs if not already done and if necessary discuss pain during insertion and its management with the patient
Action to be taken if the patient is excluded	Refer to medical staff for review and prescribing of alternative agent if appropriate. Document reason for exclusion in patient case notes.
Action to be taken if the patient or carer declines treatment	Document refusal, action taken and advice given in nursing documentation and refer to medical staff if appropriate.
Arrangements for referral for medical advice	Colposcopy and Hysteroscopy clinics are undertaken under consultant lead and the nurse specialist may contact them directly for support.

5. Description of treatment

Name, strength & formulation of drug	Intrauterine delivery system (Mirena®) consisting of T-shaped frame carrying 52mg Levonorgestrel, releasing 20micrograms/24hours
Legal category	POM
Route / method of administration	Intrauterine insertion
Indicate any off-label use (if relevant)	The Faculty of Sexual and Reproductive Healthcare (FSRH) advises levonorgestrel is used as detailed below, although these situations are considered unlicensed: • Insertion at any time if reasonably certain the woman is not pregnant or at risk of pregnancy; • Additional precautions (e.g. barrier methods) for at least 7 days before replacement even if immediate replacement is intended; • Insertion immediately following termination of pregnancy below 24 weeks' gestation; • Postpartum insertions 4 weeks after delivery.
Dose and frequency of administration	Single administration per episode of treatment Levonorgestrel 20micrograms/24 hours.
Duration of treatment	Licensed for 5 years
Quantity to be supplied (leave blank if PGD is administration ONLY)	N/A

Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store in Gynaecology Out Patient Suite Cupboard (a locked medicines cupboard)
Drug interactions	If the patient is receiving any concomitant medication or treatment it is the responsibility of the person identified in "Staff Group" to ensure that treatment with the drug detailed in this direction is appropriate. Check all concurrent medication with the patient and in the current BNF before supplying. Refer to a doctor if the patient is taking any medication that may interact with the intended treatment. **If in any doubt advice should be sought and recorded before the drug is administered.**
Adverse reactions	• Initially, changes in the pattern and duration of menstrual bleeding(spotting or prolonged bleeding) are common • abdominal pain, expulsion, peripheral oedema, depression(sometimes severe) • nervousness, salphingitis, pelvic inflammatory disease, pelvic pain, back pain, weight gain, dysmenorrhoea • rarely uterine perforation, hirsutism, hair loss, pruritus, migraine, rash, acne, • contraceptive failure • improvement in progestogenic side-effects such as mastalgia and in the bleeding pattern usually occurs a few months after insertion and bleeding may often become very light or absent • Functional ovarian cysts(usually asymptomatic) can occur and usually resolve spontaneously (ultrasound monitoring recommended) • See GP if any adverse reactions occur.
Management of and reporting procedure for adverse reactions	• Consult medical advice if an adverse event occurs. • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • Resuscitation equipment must be available with adrenaline in the event of anaphylaxis – contact resuscitation team on 2222 if occurs.
Written information to be given to patient or carer	• Patient Information Leaflet
Patient advice / follow up treatment	• treatment benefits and alternatives (including no treatment) • a description of the device and its mode of action • a description of the insertion procedure with diagrams • the right to have the device removed without undue delay • user's right to change her mind or have a second opinion • detailed patient information leaflet

	• very common undesirable effects (occurring in more than 10% of users) include bleeding changes and ovarian cysts • warn about side effects e.g. spotting/ irregular bleeding, and that they are likely to subside with prolonged use • Common undesirable effects >1/100, <1/10; Oedema (peripheral or Abdominal), weight gain, depressive mood, nervousness, mood lability, headache, abdominal pain, pelvic pain, mastalgia, back pain, expulsion. • Very common undesirable effects (occurring in more than 10% of users) include uterine/vaginal bleeding including spotting, oligomenorrhoea, amenorrhoea. • details of follow up arrangements • card containing name of device, date of insertion, due date for replacement • day time help line • to seek immediate medical advice if becomes pregnant, has symptoms of a STI or unexplained abdominal pain • check threads each month and in case of missing threads, use condoms and see GP/doctor for urgent scan to exclude perforation or expulsion of the IUS • document that the PGD has been followed and that the patient knows and understands the risks and benefits • discuss STI screening depending on risk assessment • The FSRH supports extended use of Mirena IUS for contraception until the age of 55 if inserted at age 45 or over, provided it is not being used as the progestogen replacement therapy (HRT) for endometrial protection.
Records	The clinical nurse specialist working under the PGD, must capture/document all of the following in the patient case notes and IT system: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous.

6. Key references

Key references	• *Electronic Medicines Compendium, Mirena 20 micrograms/24 hours intrauterine delivery system, Summary of Product Characteristics* https://www.medicines.org.uk/emc/product/1132/smpc • *Electronic Medicines Compendium, Mirena 20 micrograms/24 hours intrauterine delivery system, Patient Information Leaflet* https://www.medicines.org.uk/emc/product/1132/pil • *Electronic BNF* https://bnf.nice.org.uk/ • *NICE Medicines practice guideline "Patient Group Directions"* https://www.nice.org.uk/guidance/mpg2 • *Faculty of Sexual Health & Reproductive Healthcare* https://www.fsrh.org/standards-and-guidance/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/

7. Registered health professional authorisation sheet

PGD Name [version]: Colposcopy/Hysteroscopy Gynae Outpatient - Levonorgestrel Intrauterine System (Mirena) [v1]
PGD ref: UHDB155
Valid from: 11/05/2022 **Expiry date:** 10/05/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.
It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.