University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of DINOPROSTONE
By Registered Midwives in the Maternity Unit at University Hospitals of Derby and Burton

Documentation details

Reference no:	UHDB261
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Change history

Version number	Change details	Date
3	Updated to UHDB format from QHB format	May 2023
3	Updated to include Propess® and Prostin E2® vaginal gel.	May 2023
4	Updated to change clinical condition and criteria from post mature to woman/birthing person from 37 weeks gestation	July 2024

Glossary

Abbreviation	Definition

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
Sarah Evans	Intrapartum Matron
Joanna Hurcombe	Advanced Pharmacist Education & Training, Women's and Children's
Jen Rowley	Obstetric Consultant
Francesca Raffi	Obstetric Consultant

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	n/a	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
Registered midwives within the maternity unit at UHDB.
Limitations to authorisation
N/A

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist)	**James Hooley**	**Signed copy held by Pharmacy**	**07/11/2024**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Associate Clinical Director	**Miss Jen Heslop**	**Signed copy held by Pharmacy**	**06/11/2024**
Deputy Head of Midwifery	**Sarah Evans**	**Signed copy held by Pharmacy**	**04/11/2024**
Advanced Pharmacist Education & Training, Women's and Children's	**Joanna Hurcombe**	**Signed copy held by Pharmacy**	07/11/2024

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	NMC Registered Midwife
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
Competency 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 the 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	Midwives are expected to keep themselves updated with the local guidance provided. Midwives must have completed the induction of labour competency package. Competency and registration to be maintained as per NMC and Trusts standards for mandatory and essential to role training.
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	Induction of Labour (IOL) for women/birthing people from 37 weeks gestation in accordance with trust guideline. Refer to Induction of Labour and Augmentation – Clinical Guidelines UHDB/IP/I1 - MATERNITY (OBSTETRICS AND MIDWIFERY) on Net-I, UHDB Strategies, Policies & Clinical Guidelines
Criteria for inclusion	Woman/birthing person requiring induction of labour from 37 weeks gestation where an Obstetric Registrar/Consultant has documented within the patient notes that Dinoprostone can be administered by a midwife. Applicable from 37 weeks gestation in patients of 18 years and older.

Criteria for exclusion	Dinoprostone should not be used or left in place if:
	• Hypersensitivity to the active substance(s) or to any of the excipients
	• When labour has started.
	• When oxytocic drugs and/or other labour induction agents are being given.
	• When strong prolonged uterine contractions would be inappropriate such as in patients:
	  ○ who have had previous major uterine surgery, e.g. caesarean section, myomectomy etc
	  ○ who have had previous major uterine cervix surgery (e.g. other than biopsies and cervical abrasion) or rupture of the uterine cervix
	  ○ with cephalopelvic disproportion
	  ○ with fetal malpresentation
	  ○ with suspicion or evidence of fetal distress or fetal compromise
	• When there is current pelvic inflammatory disease unless adequate prior treatment has been instituted.
	• When there is hypersensitivity to dinoprostone or to crosslinked macrogol (hydrogel) or Polyester yarn.
	• When there is placenta previa or unexplained vaginal bleeding during the current pregnancy.
	• Suspicion of placental abruption
	• Patients with active cardiac, pulmonary, renal or hepatic disease

Cautions including any relevant action to be taken	• History of uterine hypertony • Glaucoma or raised intra-ocular pressure • Asthma or a history of asthma • Epilepsy or a history of epilepsy • Multiple pregnancy • Pulmonary, renal or hepatic disease • Hypertension • Patients with ruptured membranes. • Women with more than 3 full term deliveries • Medication of non-steroidal anti-inflammatory drugs should be stopped before administration. • Diseases that affect metabolism or excretion of dinoprostone e.g.

	lung, liver or renal disease. • Women with an increased risk of disseminated intravascular coagulation (DIC) i.e. ○ ≥35 years of age ○ Gestational diabetes ○ Arterial hypertension ○ Hypothyroidism ○ Gestation >40 weeks. • If a caution applies but the patient has been already reviewed by a Registrar or Consultant who has confirmed prostaglandins can be administered by a midwife, a further medical review for the same condition is not required before administration or supply. Following medical advice, **the decision to administer remains with the registered midwife if administering under this PGD.** Request a prescription (PSD) from a prescriber if you are not happy to proceed under PGD.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • **Discussion with Obstetrician. A prescription (Patient Specific Direction from a prescriber) must be completed to proceed with administration when exclusions in this PGD apply.**
Action to be taken if the patient or carer declines treatment	• Document advice given • Escalate to Obstetrician for alternative plan of care.
Arrangements for referral for medical advice	Escalate to Obstetric Registrar/SHO.

5. Description of treatment

Name, strength & formulation of drug	<u>Propess 10mg vaginal delivery system</u> Each vaginal delivery system consists of a non-biodegradable polymeric drug delivery device containing 10 mg dinoprostone (Prostaglandin E2) dispersed throughout its matrix and releases approximately 0.3 mg/hour dinoprostone over a 24-hour period. Must be removed after 24 hours if not sooner. <u>Prostin E2 vaginal Gel 2mg</u> Each 3 g gel (2.5 ml) syringe contains 2 mg dinoprostone. <u>Prostin E2 vaginal Gel 1mg</u> Each 3 g gel (2.5 ml) syringe contains 1 mg dinoprostone.
Legal category	Prescription Only Medicine (POM)
Route / method of administration	<u>Propess 10mg vaginal delivery system</u> One vaginal delivery system is administered high into the posterior vaginal fornix. Once only left in situ for up to 24 hours. If the propess pessary falls out and has remained clean, i.e. dropped onto clean bed sheets and not on the floor or into the toilet, it may be reinserted and used up until ready to be removed

	If it is not possible to re-insert due to contamination, a new one may be inserted with removal/assessment not affected (24 hours after first insert). The Propess should be removed after 24 hours irrespective of whether cervical ripening has been achieved. Propess should be removed immediately in the following instances: • Where cervical dilatation has reached 4 cms • Onset of labour. For the purposes of induction of labour with PROPESS, the onset of labour is defined as the presence of regular painful uterine contractions occurring every 3 minutes irrespective of any cervical change. • Significant PV bleeding • Amniotomy. • Uterine hyperstimulation or hypertonic uterine contractions (see section below for definition and management) • Evidence of fetal compromise or distress • Evidence of maternal adverse dinoprostone effects e.g. such as nausea, vomiting, hypotension or tachycardia. • At least 30 minutes prior to starting an intravenous infusion of oxytocin In cases of spontaneous rupture of membranes, refer to UHDB guideline……. and consider removal of the Propess if appropriate <u>Prostin E2 vaginal Gel 2mg</u> In primigravida patients with unfavourable induction features (bishop score of 4 or less) 2mg should be administered vaginally. <u>Prostin E2 vaginal Gel 1mg</u> For patients who do not fit the above criteria, a 1mg dose should be administered vaginally.
Indicate any off-label use (if relevant)	*n/a*
Dose and frequency of administration	<u>Propess 10mg vaginal delivery system</u> Once only left in situ for up to 24 hours. If Prostin Gel is required, refer to and administer according to the guideline. Two doses of Prostin Gel may be administered prior to seeking a medical review. <u>Prostin E2 vaginal Gel 2mg</u> 2mg dose should be administered vaginally. Cont... <u>Prostin E2 vaginal Gel 1mg</u> 1mg dose should be administered vaginally. If a further cycle of Prostaglandins is required, the patient should first be reviewed by an Obstetric Consultant and the medication

	should be prescribed by a doctor.
Duration of treatment	As above (frequency section)
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: Propess vaginal delivery system must be stored in a freezer (-10 to -25°C). Store in the original container in order to protect from moisture. No thawing is required prior to use. Prostin vaginal gel must be stored in a refrigerator at 2-8°C.
Drug interactions	Oxytocin infusion must not be commenced with 30 minutes of removal of dinoprostone.
Identification & management of adverse reactions	Action for hyperstimulation is to remove Propess immediately as dictated by IOL policy. Hypersensitivity reactions must be reported immediately and appropriate actions taken.
Management of and reporting procedure for adverse reactions	• 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.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	To inform midwife if any adverse reactions detected.
Records	The administration of the PGD should be recorded: • ePMA (Electronic Prescribing system) UHDB Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • 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 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. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ [Accessed 26 September 2024] • Electronic BNF https://bnf.nice.org.uk/ [Accessed 26 September 2024] • NICE Medicines practice guideline "Patient Group Directions" Overview | Patient group directions | Guidance | NICE [Accessed 26 September 2024] • Induction of labour and augmentation - Clinical guidelines UHDB/IP/I1 - MATERNITY (OBSTETRICS AND MIDWIFERY) Details for: Induction of Labour and Augmentation - Clinical Guideline › Trust Policies Procedures & Guidelines catalog (koha-ptfs.co.uk) [Accessed 01 October 2024]

University Hospitals of Derby and Burton NHS Foundation Trust

Registered health professional authorisation sheet

PGD Name Maternity - Dinoprostone [v4] **PGD ref: UHDB261**
Valid from: 07/11/2024 **Expiry date: 06/11/2027**

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.