University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Mannitol 10% infusion
By Registered Nurses in Cancer at UHDB

Documentation details

Reference no:	UHDB235
Version no:	1
Valid from:	15/12/2022
Review date:	15/06/2025
Expiry date:	14/12/2025

Change history

Version number	Change details	Date
1	New template	December 2022

Glossary

Abbreviation	Definition
CDU	Chemotherapy Day Units
CTAU	Combined Triage Assessment Unit
CDCS	Cancer Diagnostics & Clinical Support Division
EPR	Electronic Patient Record
ePMA	Electronic prescribing and medicines administration
SPC	Summary of product characteristics

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
Maja Moldawa	Divisional Lead Pharmacist
Prantik Das Ian Amott	Associate Clinical Director Oncology Associate Clinical Director Haematology
Joanna Beeney	Lead Chemotherapy nurse

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 nurses who work with cancer & haematology wards and chemotherapy day units across University Hospitals Derby & Burton.
Limitations to authorisation
This organisation does not authorise the use of this PGD by any registered nurse outside of the CDCS division

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**15/12/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Lead Pharmacist	Maja Moldawa	**Signed copy held by Pharmacy**	14/12/2022
Associate Clinical Director Oncology Haematology consultant on behalf of Associate Clinical Director Haematology	Prantik Das Adrian Smith	**Signed copy held by Pharmacy** **Not required**	14/12/2022
Lead Chemotherapy nurse	Joanna Beeney	**Signed copy held by Pharmacy**	14/12/2022

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	- NMC registered nurse
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. - Training which enables the practitioner to make a clinical assessment in order to establish the need and supply the medicine according to the PGD. -Infusion Therapy Study Day if administering any IV medicines. -Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD. - Has undertaken appropriate training for working under Patient Group directive
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 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) Review/repeat initial training above when this PGD is revised
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	Maintenance of urine output >100ml/hr following cisplatin containing chemotherapy regimens in patients for whom diuresis that forms the standard chemotherapy prescription is insufficient
Criteria for inclusion	Adult patients presenting with the above scenario.
Criteria for exclusion	• Previous sensitivity or intolerance to the drug or any ingredient • Patients under 16 years old • Established anuria • severe cardiac failure • severe dehydration • severe pulmonary oedema
Cautions including any relevant action to be taken	• Extravasation causes inflammation and thrombophlebitis; monitor fluid and electrolyte balance, serum osmolality, and pulmonary and renal function; assess cardiac function before and during treatment.
Action to be taken if the patient is excluded	• Refer to medical staff for review and prescribing of alternative agent if appropriate. • Record reasons for exclusion in patient notes • Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	• Refer to medical staff for review and prescribing of alternative agent if appropriate. • Record reasons for exclusion in patient notes • Advise patient on alternative treatment
Arrangements for referral for medical advice	• If 30 minutes after the mannitol dose urine output has still not improved, contact CTAU, ACP or consultant as below • To contact combined triage assessment unit (CTAU) for assessment by advanced clinical practitioner (ACP) Or call on-call Oncologist. • Alert the crash team (cardiac arrest team 2222)

5. Description of treatment

Name, strength & formulation of drug	Mannitol 10% infusion
Legal category	POM
Route / method of administration	Intravenous infusion of 100ml over 10 minutes.
Indicate any off-label use (if relevant)	N/A
Dose and frequency of administration	• one dose (100ml) STAT • Maximum of ONE dose only to be given without a prescription. • If 30 minutes after the mannitol dose urine output has still not improved, the Consultant should be contacted for advice.

Duration of treatment	One Dose of 100ml.
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: Do not refrigerate or freeze. Visually inspect prior to use as can precipitate/crystallise at cooler temperatures.
Drug interactions	Check all concurrent medication with the patient and in the current BNF. If in any doubt advice should be sought and recorded before the drug is administered. Patients receiving concomitant ciclosporin and aminoglycoside should be closely monitored for signs of nephrotoxicity. Concomitant use of neurotoxic agents (e.g. aminoglycoside) and mannitol may potentiate the toxicity of neurotoxic agents Mannitol increases urinary excretion of lithium and therefore concomitant use of mannitol may impair the response to lithium. The development of electrolyte imbalances (e.g., hyperkalaemia, hypokalaemia) associated with mannitol administration may alter the effects of agents that are sensitive to such imbalances (e.g., digoxin, agents that may cause QT prolongation, neuromuscular blocking agents). A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Adverse reactions	Common or very common: • Cough; headache; vomiting Uncommon: Dizziness; fever; malaise; nausea; pain; skin reactions A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Monitor for sensitivity reactions. • Consult medical advice if an adverse event occurs. • Oxygen, Suction, Resuscitation trolley & Anaphylaxis box need to be available. • If reaction does not subside, seek urgent medical referral • 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 & Chemocare. • 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	Drug information leaflet can be printed from www.medicines.org.uk
Patient advice / follow up treatment	• Verbal advice on why drug administered, action of the drug and subsequent management of condition. • Warn of potential side effects. • Inform the individual/carer of possible side effects and their management. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
Records	For ePMA: Document the utilisation of the medicine under PGD on Chemocare or by ordering the appropriate drug order item on ePMA. Document the administration of the medicine. 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 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. 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/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • https://medusa.wales.nhs.uk

7. Registered health professional authorisation sheet

PGD Name [version]: Cancer – Mannitol 10% infusion [v1]
PGD ref: UHDB235

Valid from: 15/12/2022 **Expiry date: 14/12/2025**

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.