University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Glucagon 1mg injection
By Registered UHDB Staff in Adult UHDB services

Documentation details

Reference no:	UHDB026
Version no:	V1.0
Valid from:	16/09/2021
Review date:	16/03/2021
Expiry date:	15/09/2021

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	May 2021

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
James Hooley	Medicines Safety Officer (Pharmacist)
Gavin Bohan	Diabetes Safety Group Chair – The DSG have not reviewed the final document but were consulted on the need for a core PGD which they approved and requested alignment with UHDB Hypoglycaemia Guidance which has been undertaken.
Core Adult PGD list maintained by Medicines Safety Group.	Note: No PGD working group convened as this PGD is created by merging detail from multiple authorised PGDs in active use across UHDB which have been developed previously with nursing and medical input.

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
All UHDB staff providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises) This is a core PGD and <u>can</u> be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).

Limitations to authorisation
It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Chief Pharmacist	**Clive Newman**	**Signed copy held in Pharmacy**	**23/08/2021**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist) *Clinical Pharmacist from PGD working group*	**James Hooley**	**Signed copy held in Pharmacy**	**18/08/2021**
Medical Director or deputy *Doctor*	**Magnus Harrison**	**Signed copy held in Pharmacy**	**18/08/2021**
Chief Nurse or deputy *Registered Professional representing users of the PGD*	**Catherine Winfield**	**Signed copy held in Pharmacy**	**11/08/2021**

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	All Divisions, Adult Areas, registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
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 - Read the UHDB clinical guideline and/or undertaken training to manage hypoglycaemia (adult guideline on Koha)
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 the 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 It is the responsibility of the registered practitioner to keep up to date with any change to the recommendations for glucagon 1% injection or UHDB clinical guidelines for Hypoglycaemia.
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	For emergency treatment of hypoglycaemia.
Criteria for inclusion	Diabetic adults who present with signs and symptoms of hypoglycaemia (defined as a finger prick or lab glucose level of less than 4mmols/l) and then based on severity of hypoglycaemia and conscious level as per UHDB guidelines: **Moderate severity** (= conscious and can swallow but confused or aggressive): • Use glucagon where oral carbohydrates* (including glucose gel) has been considered for use but is contraindicated **Severe severity** (= unconscious, fitting or unable to take orally) : • Use glucagon where no immediate IV access is available for intravenous glucose *See references; Adult hypoglycaemia guidelines include detail on appropriate types and quantities of oral carbohydrates and glucose gel.

Criteria for exclusion	• *Patient able to take oral carbohydrates or glucose (dextrose) gel*
	• *The following patients are likely to have poor glycogen stores and will not respond to glucagon*
	  • *Adrenal insufficiency*
	  • *chronic hypoglycaemia*
	  • *Starvation*
	  • *Liver failure*
	  • *Alcohol induced hypoglycaemia*
	• *Known to have phaeochromocytoma (a neuroendocrine tumour of the medulla of the adrenal glands)*
	• *previous local or systemic reactions to the medicine*
	• *Known hypersensitivity to the active ingredient or to any component of the product - see GlucaGen Hypokit 1 mg - Summary of Product Characteristics (SmPC) - (emc)*

Cautions including any relevant action to be taken	• *Medical consultation is required for ALL patients with severe hypoglycaemia* • *If normal response within 10 minutes then provide oral carbohydrate to restore liver glycogen and prevent relapse of hypoglycaemia* • *If no response within 10 minutes* follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes - *Oral glucose to be given if possible* • **ALWAYS Refer to medical staff or prescriber** for review and prescribing of alternative agent
Action to be taken if the patient or carer declines treatment	• Document advice given and explain risks of non-treatment • **ALWAYS Refer to medical staff or prescriber** for review and prescribing of alternative agent

Arrangements for referral for medical advice	Contact your ward or clinic medical team in the first instance except in the event of anaphylaxis/cardiac arrest or where no response seen within 10 minutes when you should follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)

5. Description of treatment

Name, strength & formulation of drug	Name: Glucagon hydrochloride 1mg/ml injection (GlucaGen Hypokit) Strength: 1mg/ml Formulation: Powder and solvent for solution for intramuscular or subcutaneous injection.
Legal category	Prescription Only Medicine (POM).
Route / method of administration	Draw up the water for injections (1.1 ml) and inject into the vial containing the glucagon compacted powder. Shake the vial gently until the glucagon is completely dissolved and the solution is clear. Withdraw the solution back into the syringe. The reconstituted solution appears clear and colourless and forms an injection of 1 mg per ml to be administered **intramuscularly (IM is preferred route in UHDB guidelines)**. The subcutaneous route is licensed and may be used if IM injection is not possible or appropriate.
Indicate any off-label use (if relevant)	none
Dose and frequency of administration	• Adult: 1mg If normal response within 10 minutes then provide oral carbohydrate as per hypoglycaemia guidelines to restore liver glycogen and prevent relapse of hypoglycaemia. If no response within 10 minutes, follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures) as IV glucose must be prescribed and given. Glucagon dose should not be repeated- failure to respond implies inadequate glycogen stores.
Duration of treatment	STAT dose only
Quantity to be supplied (leave blank if PGD is administration ONLY)	n/a
Storage	**Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website as below:** Do not freeze. GlucaGen HypoKit 1 mg: GlucaGen HypoKit should be stored at a temperature of 2-8°C (in a

	refrigerator). Store in the original package in order to protect from light. If, in rare cases, the reconstituted product shows any signs of fibril formation (viscous appearance) or insoluble matter, it should be discarded. **GlucaGen Hypokit 1 mg - Summary of Product Characteristics (SmPC) - (emc)**
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: • Indomethacin: Glucogen may lose its ability to raise blood glucose or may even produce hypoglycaemia • Warfarin: glucagon may increase anticoagulant effect • Beta-blockers: Patients taking beta-blockers might be expected to have a greater increase in both pulse and blood pressure, an increase of which will be temporary because of glucagon's short half-life. The increase in blood pressure and pulse rate may require therapy in patients with coronary artery disease. • Interactions between GlucaGen and other drugs are not known when GlucaGen is used in the approved indications. **A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: GlucaGen Hypokit 1 mg - Summary of Product Characteristics (SmPC) - (emc)**
Identification & management of adverse reactions	Glucagon side effects. • Occasionally nausea and vomiting. • Abdominal pain, hypertension, hypotension, tachycardia and Hypersensitivity reactions including anaphylactic reaction/shock occur very rarely. **A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: GlucaGen Hypokit 1 mg - Summary of Product Characteristics (SmPC) - (emc)**
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	• Provide the patient with the manufacturers patient information leaflet provided with the medicine. **https://www.medicines.org.uk/emc/files/pil.1289.pdf**

Patient advice / follow up treatment	After severe hypoglycaemic event, the patient's ability to concentrate and react may be impaired. Therefore the patient should not drive or operate machinery until the patient has stabilised. Medical consultation is required for all patients with severe hypoglycaemia.
Records	For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area. For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable. Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. 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/ GlucaGen Hypokit 1 mg - Summary of Product Characteristics (SmPC) - (emc) • Electronic BNF https://bnf.nice.org.uk/ GLUCAGON | Drug | BNFc content published by NICE • Diabetes UK What is hypoglycaemia? | Signs and symptoms | Diabetes UK • UHDB Adult Clinical Guideline – Hypoglycaemia.

7. Registered health professional authorisation sheet

PGD Name [version]: Administration of Glucagon 1mg injection [v1.0] PGD ref:UHDB026

Valid from: 16/09/2021 Expiry date: 15/09/2024

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.