University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Insulin in Adult Diabetes Outpatient Clinics at University Hospitals of Derby & Burton

Documentation details

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Change history

Version number	Change details	Date
2	Extra insulin Added	22/11/22

Glossary

Abbreviation	Definition
DSN	Diabetes Specialist Nurse
DSD	Diabetes Specialist Dietitian
QHB	Queens Hospital Burton
FNCH	Florence Nightingale Community Hospital

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
Dr Emma Robinson	Endocrine and Diabetes Consultant
James Kerr	Pharmacist
Katy Gerrard	DSN

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
UHDB Diabetes outpatient clinics (at time of writing these are at FNCH and at QHB sites but can be expanded to adult services following the same framework in future)

Limitations to authorisation
Practitioners: This organisation only authorises the specific registered practitioners in section 3 of this PGD who are members of the adult diabetes team. Restrictions for dose adjustment: This PGD cannot cover adjustment of doses for medication already in a patient's possession as this does not constitute a supply or administration. Follow the separate UHDB diabetes service protocol for agreed dose adjustment practice. Restrictions on managing diabetes long term: *'PGDs are not intended for the management of long-term conditions or the long-term, repeat supply of medicines to individuals to manage a long term condition'* [NICE guidance; Specialist Pharmacy Service]. At UHDB, this PGD therefore authorises administration or supply ONLY after a diagnosis of Diabetes Mellitus by a doctor. **The PGD will only be used for short-term supply (max 1 month) to bridge until a GP/hospital prescription can be issued** and this will be either: a) Following new diagnosis from a doctor - there are quality & safety benefits to a PGD pathway in this scenario (if a prescription can't be obtained). The patient has a chance to discuss insulin and device with a specialist nurse/dietician and receive full counselling or demonstration b) When an insulin type/brand/device needs to be changed

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer*	James Hooley	**Signed copy held by Pharmacy**	**18/05/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Lead Pharmacist (Medicine) *Clinical Pharmacist from PGD working group*	James Kerr	**Signed copy held by Pharmacy**	**03/05/2023**
Consultant in Diabetes *Doctor*	Dr Emma Robinson	**Signed copy held by Pharmacy**	**20/04/2023**
Lead Diabetes Specialist Nurse *Registered Professional representing users of the PGD*	**Lisa Stone**	**Signed copy held by Pharmacy**	**16/05/2023**

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 - Registered Dietitian
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 - DSD/DSN competencies have been signed off regarding insulin initiation and dose titration
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	Treatment of diabetes mellitus in adult patients who are newly diagnosed with diabetes requiring insulin treatment or require a change of insulin product/type or change in device.
Criteria for inclusion	Adult patients with diabetes mellitus reviewed at Diabetes Outpatient clinics in the Hospital or Community setting. *Insulins can only be supplied to patients with an established diagnosis of diabetes confirmed by a doctor
Criteria for exclusion	Patients who do not have an established diagnosis of diabetes confirmed by a doctor. Patients presenting to clinic who require insulin dose adjustments - **refer to separate protocol for Insulin dose adjustments*.* History of persistent hypoglycaemia. Hypersensitivity to any of the insulins listed below or to the formulation excipients, unless used as part of a desensitisation programme. Under no circumstances should this formulation be given intravenously. Children under the age of 18.
Cautions including any relevant action to be taken	* For insulin dose adjustments – see separate protocol* Where further clarification or advice is required when commencing a patient on a new class of medication, this should be discussed with a doctor. Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. Usually the first symptoms of hyperglycaemia develop gradually over a period of hours or days. They include thirst, increased frequency of urination, nausea, vomiting, drowsiness, flushed dry skin, dry mouth, and loss of appetite as well as acetone odour of breath. In type 1 diabetes, untreated hyperglycaemic events eventually lead to diabetic ketoacidosis, which is potentially lethal. A specific overdose for insulin cannot be defined; however, hypoglycaemia may develop over sequential stages if too high doses relative to the patient's requirement are administered. Before travelling between different time zones the patient should seek a healthcare professional’s advice since this may mean that the patient has to take the insulin and meals at different times.

Transfer from other insulin medicinal products

Transferring a patient to another type or brand of insulin should be done under health professional supervision. Changes in strength, brand (manufacturer), type (soluble, isophane, mixture), species (animal, human, human insulin analogue), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.

Some patients taking human insulin may require a change in dosage from that used with animal-source insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months.

Hypoglycaemia

A few patients who experienced hypoglycaemic reactions after transferring insulin have reported that the early warning symptoms were less pronounced or different from those experienced with their previous animal insulin. Patients whose blood glucose is greatly improved, e.g., by intensified insulin therapy, may lose some or all of the warning symptoms of hypoglycaemia and should be advised accordingly. Other conditions which may make the early warning symptoms of hypoglycaemia different or less pronounced include long duration of diabetes, diabetic nerve disease, or medications such as beta-blockers. Uncorrected hypoglycaemic and hyperglycaemic reactions can cause loss of consciousness, coma or death.

Combination of Insulin with pioglitazone

Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind if treatment with the combination of pioglitazone and insulin is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs.

Pregnancy

It is essential to maintain good control of the insulin-treated (insulin-dependent or gestational diabetes) patient throughout pregnancy. Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients with diabetes should be advised to inform their doctors if they are pregnant or are contemplating pregnancy.

Careful monitoring of glucose control, as well as general health, is essential in pregnant patients with diabetes.

	Patients with diabetes who are lactating may require adjustments in insulin dose and/or diet. Intercurrent illness Intercurrent illness requires intensified metabolic monitoring. In many cases tests for ketones are indicated, and often it is necessary to adjust the insulin dose. The insulin requirement is often increased. Patients with type 1 diabetes must continue to consume at least a small amount of carbohydrates and fluids on a regular basis; even if they are able to eat only little or no food, or are vomiting etc. and they must never omit insulin entirely. Driving/operating machinery The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or using machines). Patients should be advised to take precautions to avoid hypoglycaemia while driving. This is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances. Medication errors Medication errors have been reported in which other insulins, particularly short-acting insulins, have been accidentally supplied/administered instead of long-acting insulins (or vice versa). Therefore, both the insulin product and label must always be checked before each supply/administration to avoid medication errors between different types/brands of insulin.
Action to be taken if the patient is excluded	• Advise patient on alternative treatment • Record reason for exclusion in patient notes • Discuss with consultant
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Discuss with consultant
Arrangements for referral for medical advice	• Discussion with patient about reason for referral • Documented in patient notes

5a. Description of treatment

Name, strength & formulation of drug	Biphasic isophane and analogue insulins in the form of: • Humulin M3 Kwikpen 100 Units/ml solution for injection in 3ml pre-filled pen. • Novomix 30 Flex Pen 100units/ml solution for injection in 3ml pre-filled pen • Humalog Mix 50 KwikPen 100units/ml solution for injection in 3ml pre-filled pen • Humalog Mix 25 KwikPen 100units/ml solution for injection in 3ml pre-filled pen
Legal category	POM
Route / method of administration	Biphasic insulins should be given by subcutaneous injection. This formulation should not be administered intravenously. Subcutaneous administration should be in the thighs, buttocks or abdomen. Use of injection sites should be rotated so that the same site is not used more than approximately once a month. Care should be taken when injecting any insulin preparations to ensure that a blood vessel has not been entered. After any insulin injection, the injection site should not be massaged. Patients must be educated to use proper injection techniques. Biphasic formulations are a ready-made defined mixture of soluble and isophane/analogue insulin designed to avoid the need for the patient to mix insulin preparations. A patient's treatment regimen should be based on their individual metabolic requirements. The mixture must be agitated to ensure it is homogenous prior to injection. **All products are accompanied by a package leaflet with detailed instructions for use to be followed.**
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	The dosage should be determined by a Diabetes Specialist Nurse or Dietitian, according to the requirement of the patient. Biphasic insulin dosing is individual and determined in accordance with the needs of the patient. Blood glucose monitoring and insulin dose adjustments are recommended to achieve optimal glycaemic control. In patients with type 2 diabetes biphasic insulin can be given as monotherapy. Biphasic insulin can also be given in combination with oral antidiabetic medicinal products if the patient's blood glucose is inadequately controlled with oral antidiabetic medicinal products alone.

	Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirements. Concomitant diseases in the kidney, liver or affecting the adrenal, pituitary or thyroid gland can require changes in insulin dose
Duration of treatment	No limit on duration of treatment. Patient can be provided with one initial supply for a maximum treatment time of one month – further supplies must be prescribed by the General Practitioner (GP).
Quantity to be supplied (leave blank if PGD is administration ONLY)	The minimum needed to allow the patient time to get regular supply from their GP (dose dependant but usually no more than 2 pens).
Storage	Stock must be securely stored in a fridge according to UHDB medicines policy and in conditions in line with SPC.
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. If in any doubt advice should be sought and recorded before the drug is administered. 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. A number of medicinal products are known to interact with glucose metabolism and therefore the physician should be consulted when using other medications in addition to human insulin (see section 4.4). The clinician must therefore take possible interactions into account and should always ask his patients about any medicinal products they take. Insulin requirements may be increased by substances with hyperglycaemic activity, such as glucocorticoids, thyroid hormones, growth hormone, danazol, beta$_2$-sympatomimetics (such as ritodrine, salbutamol, terbutaline), thiazides. Insulin requirements may be reduced in the presence of substances with hypoglycaemic activity, such as oral hypoglycaemics (OHA), salicylates (for example, acetylsalicylic acid), certain antidepressants (monoamine oxidase inhibitors), certain angiotensin-converting enzyme (ACE) inhibitors (captopril, enalapril), angiotensin II receptor blockers, non-selective beta-blocking agents, and alcohol. Somatostatin analogues (octreotide, lanreotide) may both decrease or increase insulin dose requirements.

	A detailed list of interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Adverse reactions	The use of dosages which are inadequate, or discontinuation of treatment, especially in insulin-dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis, conditions which are potentially lethal. Treatment with biphasic insulin may cause formation of antibodies, but titres of antibodies are lower than those to purified animal insulin. Insulin requirements may change significantly in diseases of the adrenal, pituitary, or thyroid glands, and in the presence of renal or hepatic impairment. Insulin requirements may be increased during illness or emotional disturbances. Adjustment of insulin dosage may also be necessary if patients change their level of physical activity or change their usual diet. Combination of human insulin with pioglitazone Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind, if treatment with the combination of pioglitazone and human insulin is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued, if any deterioration in cardiac symptoms occurs. Hypoglycaemia: The most frequently reported adverse reaction is hypoglycaemia. It may occur if the insulin dose is too high in relation to the insulin requirement. Severe hypoglycaemia may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death. The symptoms of hypoglycaemia usually occur suddenly. They may include cold sweats, cool pale skin, fatigue, nervousness or tremor, anxiousness, unusual tiredness or weakness, confusion, difficulty in concentration, drowsiness, excessive hunger, vision changes, headache, nausea and palpitation. Anaphylactic reactions: The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in

	breathing, palpitation and reduction in blood pressure) is very rare but can potentially be life threatening. Lipodystrophy: Lipodystrophy is reported as uncommon. It may occur at the injection site; therefore it is recommended to rotate injection sites within an area. 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	• 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	Monitor for sensitivity reactions; Always provide the manufacturer's Patient Information Leaflet and any specific local/national service leaflets *(sensitively ensure patient is able to read and understand, if not then cover verbally)*; Verbal advice on why drug administered, action of the drug and subsequent management of condition; Explain treatment and any further instructions to aid compliance. Advise patient to seek medical advice in case of severe or unexplained adverse effects, or if treatment fails or conditions worsens Check Blood Glucose levels prior to driving and physical activity. Store in a fridge until use-by date. However, when the insulin is in use, it should be kept out of the fridge (less than 30°C) for a maximum of 28 days. Advise to inform the DVLA if patient drives. Diabetes Specialist Nurse (DSN)/Dietitian to provide their contact details for patient. DSN/Dietitian to provide their contact details for patient Patient should also be given insulin pen needles and a sharps box and advised regarding safe disposal of sharps.
Records	A record of the supply of this medication should be documented either in the patients paper medical notes or within their EPMA record. 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.

5b. Description of treatment

Name, strength & formulation of drug	**Rapid acting insulins** • NovoRapid Penfill 100 units/ml solution in cartridge • NovoRapid 100 units/ml in10ml vial • NovoRapid FlexPen 100 units/ml solution for injection in pre-filled pen • Fiasp FlexTouch 100 units/ml solution for injection in pre-filled pen • Humalog 100 units/ml in 10 ml vial • Humalog Kwikpen 100 units/ml in pre-filled pen
Legal category	POM
Route / method of administration	NovoRapid, Humalog and Fiasp are rapid-acting insulin analogues. They can be administered subcutaneously by injection in the abdomen, the thigh or the gluteal region or for use within and insulin pump. Injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy. As with all insulin medicinal products, subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites. Compared to soluble human insulin the faster onset of action of these insulins are maintained regardless of the injection site. As with all insulin medicinal products, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. NovoRapid or Humalog should be given approximately 15 minutes before food. Fiasp should be given from 5 minutes to immediately before food.

	NovoRapid and Humalog 100 unit/ml 10ml vials can be used for insulin pump therapy **All products are accompanied by a package leaflet with detailed instructions for use to be followed.**
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	The dosage should be determined by a Diabetes specialist Nurse or Dietitian, according to the requirement of the patient. Dosing is individual and determined in accordance with the needs of the patient. It should normally be used in combination with intermediate-acting or long-acting insulin given at least once a day. Blood glucose monitoring and insulin dose adjustments are recommended to achieve optimal glycaemic control. The individual insulin requirement in adults is usually between 0.5 and 1.0 unit/kg/day. In a basal-bolus treatment regimen 50-70% of this requirement may be provided by quick acting insulin and the remainder by intermediate-acting or long-acting insulin. Adjustment of dosage may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness. Dosage is generally related to carbohydrate intake and rapid acting insulins can be taken whenever carbohydrates are eaten. When NovoRapid, Humalog or Fiasp is injected subcutaneously, the onset of action will occur within 5 to 20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after injection. The duration of action is 3 to 5 hours.
Duration of treatment	No limit on duration of treatment. Patient can be provided with one initial supply for a maximum treatment time of one month – further supplies must be prescribed by the General Practitioner (GP).
Quantity to be supplied (leave blank if PGD is administration ONLY)	The minimum needed to allow the patient time to get regular supply from their GP (usually no more than 2 pens).
Storage	Stock must be securely stored in a fridge according to UHDB medicines policy and in conditions in line with SPC.
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. If in any doubt advice should be sought and recorded before the drug is administered.

	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. A number of medicinal products are known to interact with glucose metabolism and therefore the physician should be consulted when using other medications in addition to human insulin (see section 4.4). The clinician must therefore take possible interactions into account and should always ask his patients about any medicinal products they take. Insulin requirements may be increased by substances with hyperglycaemic activity, such as glucocorticoids, thyroid hormones, growth hormone, danazol, beta$_2$-sympatomimetics (such as ritodrine, salbutamol, terbutaline), thiazides. Insulin requirements may be reduced in the presence of substances with hypoglycaemic activity, such as oral hypoglycaemics (OHA), salicylates (for example, acetylsalicylic acid), certain antidepressants (monoamine oxidase inhibitors), certain angiotensin-converting enzyme (ACE) inhibitors (captopril, enalapril), angiotensin II receptor blockers, non-selective beta-blocking agents, and alcohol. Somatostatin analogues (octreotide, lanreotide) may both decrease or increase insulin dose requirements 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	At the beginning of the insulin treatment, refraction anomalies, oedema and injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching at the injection site) may occur. These reactions are usually of transitory nature. Fast improvement in blood glucose control may be associated with acute painful neuropathy, which is usually reversible. Intensification of insulin therapy with abrupt improvement in glycaemic control may be associated with temporary worsening of diabetic retinopathy, while long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy. Hypoglycaemia: The most frequently reported adverse reaction is hypoglycaemia. It may occur if the insulin dose is too high in relation to the insulin requirement. Severe hypoglycaemia may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death. The symptoms of hypoglycaemia usually occur suddenly. They may include cold sweats, cool pale skin, fatigue, nervousness or tremor, anxiousness, unusual tiredness or weakness, confusion, difficulty in concentration, drowsiness, excessive hunger, vision changes, headache, nausea and palpitation.

	Anaphylactic reactions: The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure) is very rare but can potentially be life threatening. Lipodystrophy: Lipodystrophy is reported as uncommon. It may occur at the injection site; therefore it is recommended to rotate injection sites within an area. **This list may not represent all reported side effects of this medicine. For further information please refer to the BNF or SPC**
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	• Monitor for sensitivity reactions; • Always provide the manufacturer's Patient Information Leaflet and any specific local/national service leaflets (sensitively ensure patient is able to read and understand, if not then cover verbally); • Verbal advice on why drug administered, action of the drug and subsequent management of condition; • Explain treatment and any further instructions to aid compliance. • Advise patient to seek medical advice in case of severe or unexplained adverse effects, or if treatment fails or conditions worsens • Check Blood Glucose levels prior to driving and physical activity. • Store in a fridge until use-by date. However, when the insulin is in use, it should be kept out of the fridge (less than 30°C) for a maximum of 28 days. • Advise to inform the DVLA if patient drives. • Diabetes Specialist Nurse (DSN)/Dietitian to provide their contact details for patient. DSN/Dietitian to provide their contact details for patient • Patient should also be given insulin pen needles and a sharps box and advised regarding safe disposal of sharps.
Records	A record of the supply of this medication should be documented either in the patients paper medical notes or in their EPMA record. 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.

5c. Description of treatment

Name, strength & formulation of drug	**Background Insulins (BI)** Insulin Glargine Lantus 100 units/ml Solostar prefilled pens Insulin Glargine Semglee 100 units/ml prefilled pens Insulin Degludec 100units/ml FlexTouch prefilled pens Insulin Glargine Toujeo 300 units/ml SoloStar prefilled pens Insulin Detemir Levemir 100 units/ml Flexpen prefilled pens Insulin Detemir Levemir cartridges 100 units/ml solution Insulin Glargine Abasaglar 100units/ml Kwikpen prefilled pens
Legal category	POM
Route / method of administration	BI is administered subcutaneously. BI should not be administered intravenously. The prolonged duration of action of BI is dependent on its injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycaemia. There are no clinically relevant differences in serum insulin or glucose levels after abdominal, deltoid or thigh administration of BI. Injection sites must be rotated within a given injection area from one injection to the next. BI must not be mixed with any other insulin or diluted. Mixing or diluting can change its time/action profile and mixing can cause precipitation.

	All products are accompanied by a package leaflet with detailed instructions for use to be followed.
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	The dosage should be determined by a Diabetes specialist Nurse or Dietitian, according to the requirement of the patient. Insulin glargine should be administered once daily at any time but at the same time each day. Insulin detemir should be administered twice a day, morning and evening with at least 7 hours between doses. The BI dose regimen (dose and timing) should be individually adjusted. In patients with type 2 diabetes mellitus, Lantus can also be given together with orally active antidiabetic medicinal products
Duration of treatment	No limit on duration of treatment. Patient can be provided with one initial supply for a maximum treatment time of one month – further supplies must be prescribed by the General Practitioner (GP).
Quantity to be supplied (leave blank if PGD is administration ONLY)	The minimum needed to allow the patient time to get regular supply from their GP (usually no more than 2 pens).
Storage	Stock must be securely stored in the fridge according to UHDB medicines policy and in conditions in line with SPC.
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. If in any doubt advice should be sought and recorded before the drug is administered. 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. A number of medicinal products are known to interact with glucose metabolism and therefore the physician should be consulted when using other medications in addition to human insulin (see section 4.4). The clinician must therefore take possible interactions into account and should always ask his patients about any medicinal products they take. Insulin requirements may be increased by substances with hyperglycaemic activity, such as glucocorticoids, thyroid hormones, growth hormone, danazol, beta$_2$-sympatomimetics (such as ritodrine, salbutamol, terbutaline), thiazides.

	Insulin requirements may be reduced in the presence of substances with hypoglycaemic activity, such as oral hypoglycaemics (OHA), salicylates (for example, acetylsalicylic acid), certain antidepressants (monoamine oxidase inhibitors), certain angiotensin-converting enzyme (ACE) inhibitors (captopril, enalapril), angiotensin II receptor blockers, non-selective beta-blocking agents, and alcohol. Somatostatin analogues (octreotide, lanreotide) may both decrease or increase insulin dose requirements.
Adverse reactions	Hypoglycaemia: The most frequently reported adverse reaction is hypoglycaemia. It may occur if the insulin dose is too high in relation to the insulin requirement. Severe hypoglycaemia may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death. The symptoms of hypoglycaemia usually occur suddenly. They may include cold sweats, cool pale skin, fatigue, nervousness or tremor, anxiousness, unusual tiredness or weakness, confusion, difficulty in concentration, drowsiness, excessive hunger, vision changes, headache, nausea and palpitation. Hypoglycaemia may be associated with listlessness, confusion, palpitations, headache, sweating and vomiting. Mild hypoglycaemic episodes will respond to oral administration of glucose or sugar products. Correction of moderately severe hypoglycaemia can be accomplished by intramuscular or subcutaneous administration of glucagon, followed by oral carbohydrate when the patient recovers sufficiently. Patients who fail to respond to glucagon must be given glucose solution intravenously. If the patient is comatose, glucagon should be administered intramuscularly or subcutaneously. However, glucose solution must be given intravenously if glucagon is not available, or if the patient fails to respond to glucagon. The patient should be given a meal as soon as consciousness is recovered. Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may occur after apparent clinical recovery. Anaphylactic reactions: The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure) is very rare but can potentially be life threatening.

	Lipodystrophy: Lipodystrophy is reported as uncommon. It may occur at the injection site; therefore it is recommended to rotate injection sites within an area. **This list may not represent all reported side effects of this medicine. For further information please refer to the BNF or SPC**
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	• Monitor for sensitivity reactions; • Always provide the manufacturer's Patient Information Leaflet and any specific local/national service leaflets (sensitively ensure patient is able to read and understand, if not then cover verbally); • Verbal advice on why drug administered, action of the drug and subsequent management of condition; • Explain treatment and any further instructions to aid compliance. • Advise patient to seek medical advice in case of severe or unexplained adverse effects, or if treatment fails or conditions worsens • Check Blood Glucose levels prior to driving and physical activity. • Store in a fridge until use-by date. However, when the insulin is in use, it should be kept out of the fridge (less than 30°C) for a maximum of 28 days. • Advise to inform the DVLA if patient drives. • Diabetes Specialist Nurse (DSN)/Dietician to provide their contact details for patient. • Patient should also be given insulin pen needles and a sharps box and advised regarding safe disposal of sharps.
Records	A record of the supply of this medication should be documented either in the patients paper medical notes or in their electronic records on either Lorrenzo (Derby) or V6 (Burton). 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.

5d Description of treatment

Name, strength & formulation of drug	***Medium Acting Insulins*** Isophane Insulin (Humulin I Kwikpen) 100 units/ml solution
Legal category	POM
Route / method of administration	Isophane Insulin (Humulin I) should be given by subcutaneous injection but may, although not recommended, also be given by intramuscular injection. This formulation should not be administered intravenously. Subcutaneous administration should be in the thighs, buttocks or abdomen. Use of injection sites should be rotated so that the same site is not used more than approximately once a month. Subcutaneous injection into the thigh results in a slower and less variable absorption compared to the other injection sites. Injection into a lifted skin fold minimises the risk of unintended intramuscular injection but may not be necessary with the use of short needles. The needle should be kept under the skin for at least 6 seconds to make sure the entire dose is injected. Care should be taken when injecting any HUMULIN insulin preparations to ensure that a blood vessel has not been entered. After any insulin injection, the injection site should not be massaged. Patients must be educated to use proper injection techniques. Isophane Insulins (Humulin I®) may be administered in combination with Soluble Insulin (Humulin S®) or Analogue quick acting insulins such and NovoRapid.

	A patient's treatment regimen should be based on their individual metabolic requirements. Each pack contains a patient information leaflet with instructions on how to inject insulin. The Isophane Insulin pre-filled pen (Humulin I® Kwikpen) is designed to be used with single-use universal fit pen tip needles of up to 8mm in length. **All products are accompanied by a package leaflet with detailed instructions for use to be followed.**
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	The dosage should be determined by a Diabetes Specialist Nurse or Dietitian, according to the requirement of the patient. Dosage is individual and determined in accordance with the needs of the patient. The individual insulin requirement is usually between 0.3 and 1.0 units/kg/day. The daily insulin requirement may be higher in patients with insulin resistance (e.g. during puberty or due to obesity) and lower in patients with residual, endogenous insulin production. Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirement. Renal or hepatic impairment may reduce insulin requirement.
Duration of treatment	No limit on duration of treatment. Patient can be provided with one initial supply for a maximum treatment time of one month – further supplies must be prescribed by the General Practitioner (GP).
Quantity to be supplied (leave blank if PGD is administration ONLY)	The minimum needed to allow the patient time to get regular supply from their GP (usually no more than 2 pens).
Storage	Stock must be securely stored in a fridge according to UHDB medicines policy and in conditions in line with SPC.
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. If in any doubt advice should be sought and recorded before the drug is administered.

	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. A number of medicinal products are known to interact with glucose metabolism and therefore the physician should be consulted when using other medications in addition to human insulin (see section 4.4). The clinician must therefore take possible interactions into account and should always ask his patients about any medicinal products they take. Insulin requirements may be increased by substances with hyperglycaemic activity, such as glucocorticoids, thyroid hormones, growth hormone, danazol, beta$_2$-sympatomimetics (such as ritodrine, salbutamol, terbutaline), thiazides. Insulin requirements may be reduced in the presence of substances with hypoglycaemic activity, such as oral hypoglycaemics (OHA), salicylates (for example, acetylsalicylic acid), certain antidepressants (monoamine oxidase inhibitors), certain angiotensin-converting enzyme (ACE) inhibitors (captopril, enalapril), angiotensin II receptor blockers, non-selective beta-blocking agents, and alcohol. Somatostatin analogues (octreotide, lanreotide) may both decrease or increase insulin dose requirements. 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	Hypoglycaemia is the most frequent undesirable effect of insulin therapy that a patient with diabetes may suffer. Severe hypoglycaemia may lead to loss of consciousness, and in extreme cases, death. No specific frequency for hypoglycaemia is presented, since hypoglycaemia is a result of both the insulin dose and other factors e.g., a patient's level of diet and exercise. Local allergy in patients is common (1/100 to <1/10). Redness, swelling, and itching can occur at the site of insulin injection. This condition usually resolves in a few days to a few weeks. In some instances, local reactions may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique. Systemic allergy, which is very rare (<1/10,000) but potentially more serious, is a generalised allergy to insulin. It may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalised allergy may be life-threatening. In the rare event of a severe allergy to HUMULIN, treatment is required immediately. A change of insulin or desensitisation may be required. Lipodystrophy at the injection site is uncommon (1/1,000 to <1/100).

	Cases of oedema have been reported with insulin therapy, particularly if previous poor metabolic control is improved by intensified insulin therapy. Insulin has no specific overdose definitions, because serum glucose concentrations are a result of complex interactions between insulin levels, glucose availability and other metabolic processes. Hypoglycaemia may occur as a result of an excess of insulin relative to food intake and energy expenditure. Hypoglycaemia may be associated with listlessness, confusion, palpitations, headache, sweating and vomiting. Mild hypoglycaemic episodes will respond to oral administration of glucose or sugar products. Correction of moderately severe hypoglycaemia can be accomplished by intramuscular or subcutaneous administration of glucagon, followed by oral carbohydrate when the patient recovers sufficiently. Patients who fail to respond to glucagon must be given glucose solution intravenously. If the patient is comatose, glucagon should be administered intramuscularly or subcutaneously. However, glucose solution must be given intravenously if glucagon is not available, or if the patient fails to respond to glucagon. The patient should be given a meal as soon as consciousness is recovered. Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may occur after apparent clinical recovery. **This list may not represent all reported side effects of this medicine. For further information please refer to the BNF or SPC**
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.
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	subsequent management of condition; • Explain treatment and any further instructions to aid compliance. • Advise patient to seek medical advice in case of severe or unexplained adverse effects, or if treatment fails or conditions worsens • Check Blood Glucose levels prior to driving and physical activity. • Store in a fridge until use-by date. However, when the insulin is in use, it should be kept out of the fridge (less than 30°C) for a maximum of 28 days. • Advise to inform the DVLA if patient drives. • Diabetes Specialist Nurse (DSN)/Dietitian to provide their contact details for patient. • Patient should also be given insulin pen needles and a sharps box and advised regarding safe disposal of sharps.
Records	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.

8. 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 • Derbyshire Joint Area Prescribing Guidelines BNF 6 Endocrine (derbyshiremedicinesmanagement.nhs.uk)

University Hospitals of Derby and Burton NHS Foundation Trust

9. Registered health professional authorisation sheet

PGD Name [version]: Adult Diabetes Outpatients - Supply/Administration of Insulin [v1]

PGD ref: UHDB250

Valid from: 18/05/2023 Expiry date: 17/05/2026

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.