Prescribing Points

Volume 24 Issue 7 December 2015

Oxfordshire Cinical Commissioning Group

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Diabetes Update - Special Edition

This edition includes information on recent developments in diabetes prescribing. Of particular importance are the updated **recommendations on insulin safety**. Due to the increasing range of insulins, following the recommendations is essential to avoid risk to patients.

Contents

Oxfordshire Primary Care Guideline for Insulin Initiation and Adjustment in Type 2 Diabetes

This guideline has recently been reviewed and updated, and is to be used by health care professionals who have attained competence in insulin initiation and adjustment in type 2 diabetes. The recommendations cover background, twice daily mixed and basal plus insulin regimes, and include a range of supporting information and resources. The emphasis is on more cost-effective human insulin options. The document contains links to a patient education checklist and a self-titration template which will be available via DXS. There are also links to other useful resources.

Note: we are aware of a **supply problem with Insuman insulin** products. Sanofi have advised that this should be rectified from May - July 2016. It is recommended that patients are not initiated on Insuman products until supply returns to normal. The Medicines Management Team will monitor the situation.

For Type 1 diabetes, please note that NICE NG17 updated recommendations on insulin treatment in August 2015.

New insulin and GLP1 products

Abasaglar ▼ 100units/ml (biosimilar glargine) cartridges (compatible with Humapen Savvio) and prefilled pen (KwikPen)

It is essential that glargine products are prescribed by brand name.

Abasaglar has been approved locally for initiation in patients new to insulin glargine in line with local type 2 diabetes and national type 1 diabetes guidance. This is a black triangle drug. Due to the complexity of biological substances and their production, there may be some variation in activity between biosimilars, and therefore some patients may find that there would be a difference in dosage between products. For this reason GP practice batch and pharmacy automatic **switching must not occur** between glargine products. Switching must only be carried out within a protocol of appropriate management and monitoring. Switching may be considered when the glucose management regime of an insulin glargine patient is under review for other reasons, and Abasaglar is agreed as part of a new treatment regime. Further information is available: EMA EPAR Summary for the public, EMA Q&A on Biosimilar Medicines.

Paediatrics and antenatal diabetes specialists have no immediate plans to adopt Abasaglar as an insulin glargine option.

The following insulin products are NOT to be initiated in primary care:

- **Toujeo (high strength glargine 300units/ml)**
- **Xultophy ▼ (Ideglira – degludec 100units/ml and liraglutide 3.6mg/ml fixed combination)**

Prior Approval Process for Toujeo and Xultophy. These two new insulin products should only be initiated by local diabetes consultants according to agreed criteria and following successful completion of a Prior Approval process. GP practices will be notified by the OCCG Medicines Management Team of any approved patient specific prescribing to be continued in primary care.

Reminder: **Tresiba (insulin degludec)** should only be initiated by a diabetes specialist centre in line with local guidance.

An update of the Oxfordshire Degludec Guidelines is now available on the intranet.

New GLP1 receptor agonist NOT to be initiated in primary care.

Trulicity ▼ (dulaglutide) 0.75mg and 1.5mg solution for injection in prefilled pens or syringes.

Prior Approval Process for Trulicity. This new GLP1 receptor agonist should only be initiated by local diabetes consultants according to agreed criteria and following successful completion of a Prior Approval process. GP practices will be notified by the OCCG Medicines Management Team of any approved patient specific prescribing to be continued in primary care.

An update of the Oxfordshire GLP1 Guidance is now available on the intranet.

Risk Management of diabetic ketoacidosis during treatment with SGLT2 inhibitors

Following the MHRA Drug Safety Update (June 2015) and Prescribing Points 24.5 (Sept 2015) a local risk management plan has been adopted and implemented.

Sodium-glucose co-transporter-2 (SGLT2) inhibitors (dapagliflozin, canagliflozin, empagliflozin) have been associated with cases of diabetic ketoacidosis (DKA). In Oxfordshire these drugs are for specialist diabetes consultant initiation only.

- Serious, sometimes life-threatening cases of diabetic ketoacidosis have been reported in patients on SGLT2 inhibitor treatment (canagliflozin, dapagliflozin or empagliflozin) for type 2 diabetes.
- In a number of these reports, the presentation of the condition was atypical with only moderately increased blood glucose levels observed. Such atypical presentation of diabetic ketoacidosis in patients with diabetes could delay diagnosis and treatment.
- Patients on SGLT2 inhibitors should be tested for ketones when they present with symptoms of acidosis in order to prevent delayed diagnosis and patient management.
- Cases of diabetic ketoacidosis were also reported in patients with type 1 diabetes who were given SGLT2 inhibitors. Prescribers are reminded that type 1 diabetes is not an approved indication for this drug class.

Risk Management Plan

1. Patient Information Leaflet (PIL) – available on DXS and distributed to community pharmacies
    - Advises patients of the DKA risk, and potential symptoms
    - Action if symptomatic - contact GP practice or 111 (if out of hours)
2. Letter to community and primary care healthcare professionals – available on DXS and distributed to community pharmacies
    - Summarises the risk, and prescribing information
    - Provide PIL to all SGLT2i patients
    - Check blood ketones for any SGLT2i patient presenting with symptoms suggestive of DKA regardless of blood glucose levels.
    - If blood ketone concentrations are 1 mmol/l or higher, contact the on call diabetes service via the Oxford University Hospitals NHS Foundation Trust switchboard (via 01865741166) stating that you have a patient in whom you are concerned about “SGLT2 inhibitor induced diabetic ketosis”. This service is available 24 hours per day.
    - All patients who are undergoing any surgery or procedure which will require them to be nil by mouth should stop SGLT2 inhibitors 48 hours prior to the surgery. SGLT2 inhibitors can be restarted post operatively once oral intake is back to normal.
3. Letter to colleagues in secondary care, emergency admitting services, (Emergency Department, Emergency Admission Units, Ambulance Service, Surgical Assessment Units, anaesthetists, theatres, all medical consultants and medical registrars, pharmacy), Out of Hours, NHS Pathways.
    - Summarising the risk, recommendations, and actions

It is recommended that all settings possess a blood ketone meter and in-date blood ketone test strips to ensure timely diagnosis of DKA in SGLT2i patients. This is already recommended for type 1 and pregnant diabetes patients.

NICE Type 2 Diabetes in Adults: management, NG28, December 2015

NICE have now published guidance for type 2 diabetes. The document will be reviewed locally over the next few months to clarify local recommendations and treatment options

Insulin safety - Reminder

It is essential that safety recommendations are followed regarding prescribing, storage, patient and health professional education, and provision of patient leaflet and insulin passport. Extra care is required for high strength and biosimilar insulins, as there are now 3 different glargine products on the market. **Always prescribe by brand.**

The adult patient's passport to safer use of insulin

Actions for Prescribers

For new and existing patients with diabetes prescribed insulin:

- Give the leaflet 'The Safe Use of Insulin and You' to the patient and encourage them to read it. Explain that several insulins have similar names and packaging and that the table in the leaflet is highlighting those most prone to confusion. Emphasise the importance of using the same brand of insulin, especially if using insulin glargine.
- Record that the patient information leaflet has been given. Record the appropriate Read code in the patient's notes:
- Insulin alert patient information booklet given **8CE01**
- Professional judgement not to engage patient with insulin alert requirements **8IF**
- Insulin alert patient information booklet information discussed **671F0**

The **insulin safety cards (passports),** which show a picture of the insulin device and packaging to allow for easy recognition of the correct product, are available from Eli Lilly, Novo Nordisk and Sanofi insulin companies and their local representatives. Please ensure these cards are kept in an appropriate location for practice nurses and prescribers to access when reviewing patients with diabetes and initiating insulin. Please note, Insulin safety cards are not available for animal insulin.

- Select the appropriate insulin safety card for the correct insulin AND device
- If the correct insulin safety card is not available. Give the NPSA generic insulin passport and complete the details for the insulin(s) and device prescribed
- Give to the patient and ask them to carry at all times and use it to check they have the correct insulin when receiving a prescription, when insulin is dispensed, or in situations when insulin is being given to them by another person
- Advise the patient to destroy any old cards they have
- Record that the card has been given. Relevant Read codes are:
- Insulin passport given **8CE02**
- Insulin passport completed **8BAi**
- Informed dissent not to carry insulin passport **8BAj**

Actions for pharmacists and dispensers

To avoid patients receiving duplicate insulin safety cards, it has been agreed that the cards should only be given at the point of prescribing. At the point of dispensing insulin:

- The patient should be asked for their insulin safety card (passport)
- If the patient does not have a card, explain that they should receive one at their next routine appointment
- Check the card against the product being supplied and against the prescription
- Check any discrepancies with patient/prescriber

Actions for Healthcare Professionals administering insulin

Prior to administration of insulin:

- The patient should be asked for their insulin safety card (passport)
- If the patient does not have a card, explain that they should receive one at their next routine appointment
- Check the card against the insulin to be administered and against any documentation
- Check any discrepancies with patient/prescriber

Summary table of recommendations for safe insulin use

	GPs	Nurses	Pharmacists	Care Homes	Patient/Carers
Prescribing	Ensure that insulin prescriptions are written **by brand** name, clearly and free from abbreviations. Take particular care with the word 'units'. Ensure correct injecting equipment is prescribed if necessary.	Nurse prescribers: Ensure that insulin prescriptions are written **by brand** name, clearly and free from abbreviations. Take particular care with the word 'units'. Ensure correct injecting equipment is prescribed if necessary.			
Dispensing	Dispensing practices: organise insulin stock storage to avoid picking errors. Ensure products are labelled with instructions free from abbreviations. Take particular care with the word 'units'. Ensure MAR sheets also reflect this. Provide Insulin Passport card and patient leaflet. If possible, show patient insulin dispensed prior to handing out.		Organise insulin stock storage to avoid picking errors. Ensure products are labelled clearly with instructions free from abbreviation. Take particular care with the word 'units'. Ensure MAR sheets also reflect this. Provide Insulin Passport card and patient leaflet. If possible, show patient insulin dispensed prior to handing out.		
Administration		If administering insulin to patients ensure an appropriate insulin syringe or device is used (including appropriate size). Follow guidance from NHS IQ: • **Right person** • **Right insulin** • **Right dose** • **Right device** • **Right time** • **Right way**		If administering insulin to patients ensure an appropriate insulin syringe or device is used (including appropriate size). Follow guidance from NHS IQ: • **Right person** • **Right insulin** • **Right dose** • **Right device** • **Right time** • **Right way**	If administering insulin to patients ensure an appropriate insulin syringe or device is used (including appropriate size). Follow guidance from NHS IQ: • **Right person** • **Right insulin** • **Right dose** • **Right device** • **Right time** • **Right way**
Training	All healthcare staff (including medical staff) expected to prescribe, prepare and administer insulin. Training programme available at PCDS Insulin Safety Module, Six Steps to Insulin Safety (FOC) or http://www.nhsiq.nhs.uk/8473.aspx				

Hospital admissions

Advise patients that they must ensure that they take their own insulin, whenever possible, when admitted to hospital.