Alopgliptin in adult patients with Type 2 Diabetes

The following is a consensus statement from the Diabetes Managed Clinical Network (MCN).

Alogliptin is currently the most cost effective dipeptidylpeptidase-4 inhibitor (DPP4 inhibitor (glipitin)) on the Forth Valley formulary for patients with Type 2 Diabetes Mellitus.

It is currently licensed for dual and triple therapy in adults aged over 18 years (although it has not been formally studied in combination with metformin and sulphonylureas or sodium-glucose co-transporter 2 (SGLT2) inhibitors).

The Scottish Medicines Consortium have approved its use in dual therapy, as a submission was not made for triple therapy use.

As the agents within the DPP4 class are believed to be similarly efficacious, Forth Valley Diabetes MCN support the use of Alogliptin as the DPP4 inhibitor of choice in dual and triple therapy in adult patients with Type 2 Diabetes Mellitus.

 Use Alogliptin as the DPP4 inhibitor of choice in dual and triple therapy in adult patients with Type 2 Diabetes Mellitus

Restriction on the Use of Orlistat (Xenical®)

The use of Orlisat (Xenical®) has been restricted within NHS Forth Valley due to prescribing outwith national guidance and lack of regular patient review.

Orlistat will now only be available to support those patients who are already following a structured weight management programme and are struggling to maintain weight loss.

GP consultation options for overweight patients:

 All patients should initially be signposted to the <u>Choose to Lose</u> website which provides a variety of monitoring tools and information Patients with a BMI of 35kg/m² or more with co-morbidities (e.g. diabetes, hypertension, hypercholesterolaemia) can be referred to the Weight Management Service (WMS) who will triage the referral and can provide several weight management programmes depending on patients' needs.

Referrals should be made through the SCI gateway. When navigating the gateway for the WMS you should choose Falkirk Community Hospital (FCH) then Community Dietetics.

 Orlistat should not be initiated by GPs and is now only available for patients on the recommendation of the Forth Valley Weight Management Service

Changes to Stoma Preparations

Patients may occasionally ask their GP to make a change or additions to their stoma prescriptions. This request may often be

the result of a free sample that the patient has obtained from an open day or call directly to a manufacturer or delivery company.

- It is recommended any changes to stoma preparations are **only** made on the recommendation of the stoma nurse
- Should you have any patient specific queries the stoma care nurses can be contacted on 01324 566299.

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Please Circulate to All Staff

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Key Points of interest:

- Alogliptin DPP4 inhibitor of choice in dual and triple therapy
- Orlistat should not be initiated by GPs
- Changes to stoma preprations must be recommended by stoma nurse
- Prostap DCS® first line
 LHRH agonist in prostate
 cancer for new patients
- Aprimelast must be prescribed by dermatologists
- Etoricoxib recommended starting dose for RA and AS is now 60mg



Prostap DCS[®] First line LHRH agonist in prostate cancer for new patients

The three urological cancer Managed Clinical Networks (MCNs) in Scotland were asked to make a recommendation for the first line LHRH agonist in prostate cancer for new patients.

All LHRH agonists were considered equally clinically effective through a class effect. The decision was made based on the annual treatment cost for the medicine, licensed indications, safety and range of products to cover the most frequently prescribed frequency of administration-12 weekly/3monthly or 6 monthly.

The Forth Valley Area Drug and Therapeutics Committee has recently ratified the national consensus recommen-

dation of using Leuprorelin (**Prostap DCS**[®] brand) as the preferred LHRH agonist in prostate cancer for **new** patients.

The generic descriptions are similar for the 3.75mg strength **monthly pack** of Prostap DCS[®] and the competitor product Lutrate[®] 3.75mg.

It is therefore vital that the product is prescribed by BRAND name to ensure the correct product is prescribed and dispensed.

The Forth Valley Emis formulary lists Prostap DCS [®] by **brand** name.

- Leuprorelin (Prostap DCS®) is the recommended LHRH agonist agent for first-line use in prostate cancer for new patients
- Prescribe by **BRAND** name as the generic descriptions may give rise to confusion
- Community pharmacies should confirm any prescriptions written generically as leuprorelin with the prescriber to ensure that the patient receives the correct product

Prescribing of Apremilast for severe chronic plaque psoriasis in adults

Apremilast is available in NHS Forth Valley Formulary for the treatment of moderate to severe chronic plaque psoriasis in adult patients who have:

failed to respond to, or have a contra-indication to, or are intolerant of, other systemic therapy including:

- narrow band ultraviolet B,
- psoralen and ultraviolet- A (PUVA),
- acitretin
- methotrexate
- ciclosporin

The initiation and prescribing of Apremilast will be carried out by **Consultant Dermatologists** experienced in the diagnosis and treatment of psoriasis (or psoriatic arthritis). These consultants will use HBP (Hospital Blue Pad) prescriptions for the patient to take to their community pharmacy of choice to have it dispensed.

Prescribing Information for Apremilast

The recommended dose is 30mg orally twice daily, with an initiation schedule when commencing treatment. Most common adverse reactions reported are gastrointestinal disorders, particularly diarrhoea and nausea. Other reported side-effects include decreased appetite, insomnia, suicidal ideation and depression, migraine, cough, back pain and fatigue. In severe renal impairment dosage should be reduced to 30mg once daily.

The use of strong CYP3A4 enzyme inducers (eg rifampicin, phenobarbitol, carbamazepine, phenytoin and St John's Wort) with apremilast is not recommended as they decrease the effect of apremilast.

Monitoring of the patient will be undertaken by the secondary care dermatology clinic. This will consist of U and Es, weight, patient's mood and Psoriasis Area and Severity Index (PASI) score

- In NHS Forth Valley, apremilast must only be prescribed by consultant dermatologists
- GP practices should add apremilast to the patient's medication record indicating that it has been prescribed as an "outside issue". Apremilast prescriptions **should not** be generated by GP practices
- Monitoring of patients on aprelimast will be done by the dermatology clinic
- Dermatology will stop apremilast if there has not been a minimum of 75% reduction in PASI score at 16 weeks



EMIS—enhancements to Private and Outside Prescriptions

Back in <u>December 2011</u> we issued advice on the recording of medicines which are prescribed through hospital. When a patient is given a drug prescribed only in hospital (e.g. clozapine, biosimilar drugs etc), it is good practice to record this on the patient's prescribing record in EMIS so that any interactions can be highlighted. However, it is also important that such a drug is not requested and issued from the practice as a repeat prescription inappropriately on a GP10. The same applies to Private Prescriptions, which should not be issued inappropriately on a GP10.

Stricter controls have now been put in place by EMIS to prevent private scripts or 'Outside' scripts from being printed in error on a GP10 to enhance patient safety.

The following changes have now been put in place:

- Default pharmacy text is now displayed and printed for medication that has been issued as private or outside.
 - ♦ For PRIVATE medication: PRIVATE PRESCRIPTION.
 - ♦ For OUTSIDE medication: 'SUPPLIED ELSEWHERE NOT TO BE PRESCRIBED BY GP OR DISPENSED BY COMMUNITY PHARMACY'
- PRIVATE and OUTSIDE medication can only be issued using I-Issue and re-issue of these medications will default to the correct issue type (Private or Outside).
- It is no longer possible to post-date, alter, restart, re-authorise medication that has been issued as private or outside.
- A new section entitled 'MEDICATION ISSUED ELSEWHERE' now appears on the repeat slip, listing 'Outside'medication.

Supporting documents are available within EMIS PCS (PCS00777 and PCS00774) via the Help menu.

Drug Safety Updates

Selected highlights from recent Drug Safety Update Bulletins from the MHRA (https://www.gov.uk/drug-safety-update)

Prescribers are encouraged to subscribe directly to the Drug Safety Updates Bulletin which is only available by email. www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup

Levonorgestrel-interactions with hepatic enzyme inducers

Levonorgestrel-containing emergency contraception (EC) is used to prevent unintended pregnancy.

The concomitant use of liver enzyme inducers increases the metabolism of levonorgestrel and may reduce the contraceptive efficacy. Elevated levels of CYP3A4 liver enzymes can persist for up to 4 weeks after cessation of the enzyme-inducing medicine.

Examples of enzyme inducers that reduce plasma levonorgestrel levels

Some medicines used to treat:

- epilepsy (eg. barbiturates, primidone, phenytoin, fosphenytoin, carbamazepine, eslicarbazepine, oxycarbazpine, rufinamide, topiramate)
- tuberculosis (eg, rifampicin, rifabutin)
- HIV (eg. ritonavir, efavirenz)
- fungal infections (eg. griseofulvin)
- Others (eg. modafanil, bosentan, aprepitant)

Women seeking emergency contraception who have used cytochrome P450 3A4 (CYP3A4) enzyme inducers within the last 4 weeks, should:

- preferably use a non-hormonal emergency contraceptive—ie, a copper intrauterine device. If this is not an option, double the usual dose of levonorgestrel from 1.5 milligrams to 3 milligrams
- For these women:
 - provide advice on highly effective ongoing contraception that is not affected by hepatic enzyme-inducing drugs
 - advise them to have a pregnancy test to exclude pregnancy after use of levonorgestrel-containing EC
 - advise them to seek prompt medical advice if they do become pregnant
 - please note that Ulipristal acetate is not an option in this population



Posaconazole (Noxafil $^{\rm e}$) tablets and suspension are not interchangeable

Posaconazole (Noxafil) is a broad-spectrum triazole antifungal for the treatment and prevention of fungal infections. Posaconazole **tablets and oral suspension are not interchangeable** because of differences between the two forms in dosing frequency, administration with food, and plasma drug levels achieved. Switching from posaconazole oral solution to tablets has resulted in cases of dose-related toxicity, whereas switching from tablets to oral solution has resulted in underdosing and lack of efficacy. See <u>September 2016 Update</u> for more information.

- Posaconazole tablets and oral suspension are not directly interchangeable
- Prescribers should specify the dosage form for posaconazole on every prescription
- Pharmacists should ensure that the correct oral form is dispensed to patients

Etoricoxib (Arcoxia): revised dose recommendation for rheumatoid arthritis and ankylosing spondylitis

Etoricoxib is a selective COX-2 inhibitor class of drugs and may be associated with an increased risk of coronary and cerebrovascular thrombotic events, heart failure, hypertension, and oedema (compared with placebo and some non-steroidal anti-inflammatory drugs).

Evidence has shown that the 60-mg dose is effective in rheumatoid arthritis and ankylosing spondylitis. However, for some patients, the 90-mg dose will be more efficacious, although prediction of which patients might benefit from the higher dose is not possible. See October 2016 Update for more information.

- The recommended starting dose for etoricoxib for the treatment of rheumatoid arthritis and ankylosying spondylitis is now 60mg (used to be 90mg)
- There is an option to increase the dose to 90mg, if necessary. Once clinically stable—consider down titration to 60mg daily
- The lowest effective daily dose should be used and the need for treatment regularly reassessed
- The dose in OA remains at 30mg once daily, increased if necessary to 60mg daily
- Forth Valley formulary first choice COX-2 is celecoxib

Drug Safety Updates you may have missed

Topical miconazole, including oral gel: reminder of potential for serious interactions with warfarin Serious bleeding events in patients taking miconazole and warfarin have been reported. Miconazole, including the topical gel formulation and any other topical formulations, can enhance the anticoagulant effect of warfarin—if miconazole and warfarin are used concurrently, the anticoagulant effect should be carefully monitored and, if necessary, the dose of warfarin reduced. See June 2016 Update for more information. Suspected drug interactions between miconazole and warfarin should be reported to us on a Yellow Card.

Canagliflozin (Invokana ® ▼, Vokanamet ® ▼): A signal of increased lower limb amputation (primarily of the toe) in people taking canagliflozin compared with placebo was observed in the CANVAS clinical trial in high cardiovascular risk patients and is currently under investigation. For patients on canagliflozin, consider stopping if the patient develops a significant lower limb complication (eg, skin ulcer, osteomyelitis, or gangrene), carefully monitor patients who have risk factors for amputation (eg, previous amputations, existing peripheral vascular disease, or neuropathy), monitor all patients for signs and symptoms of water or salt loss. Remember that diuretics can exacerbate dehydration. See June 2016 Update for more information.

Contact Information:

General Primary Care Prescribing Advice: Contact your Primary Care Pharmacist; or alternatively Primary Care Prescribing Support Team on 01324 673611 For Advice Related to Management of Controlled Drugs: Kirsty Peacock, Inspection Officer for Controlled Drugs, NHS Forth Valley, Forth Valley Royal Hospital Tel: 01324-566743