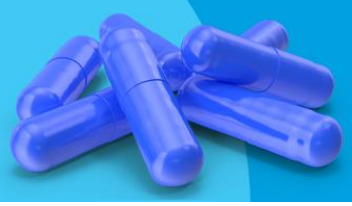
Medicines Management newsletter

Issue 17– September 2019

NHS
Halton Clinical Commissioning Group



Area Prescribing Committee

RECOMMENDATIONS, FORMULARY AND GUIDELINES

Flash Glucose Monitor (Freestyle Libre®)

For noting: factual update to flash glucose monitor statement, removing note that flash glucose monitoring does not fit DVLA guidelines for measuring glucose for driving purposes. DVLA now states from Feb. 2019 that flash glucose monitoring is suitable for measuring glucose for driving purposes in specific circumstances.

BLACK Poly-biotic sachets (VSL#3®) for Pouchitis

No longer prescribable on FP10 prescription.

BLACK EVOLOCUMAB injection (Repatha SureClick® ▼) for reduction of cardiovascular risk in adults with established atherosclerotic cardiovascular disease

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of EVOLOCUMAB injection (Repatha SureClick® ▼) for reduction of cardiovascular risk in adults with established atherosclerotic cardiovascular disease.

BLACK VORICONAZOLE (VFEND®) or POSACONAZOLE (Noxafil®) for allergic bronchopulmonary aspergillosis

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of voriconazole or posaconazole, by GPs or specialists, for allergic bronchopulmonary aspergillosis.

BLACK RUBEFACIENTS (excluding topical NSAIDS and capsaicin)

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of RUBEFACIENTS (excluding topical NSAIDS and capsaicin).

GREEN Acetylcysteine effervescent tablets (NACSYS®)

Addition as an alternative mucolytic in COPD to carbocisteine. Simplified dosing schedule. Likely to be cost saving compared to carbocisteine, up to minus £900 to £14,000 per 100,000 population depending on extent of switching to acetylcysteine and the dose of carbocisteine used. N.B. MUST be prescribed as NACSYS brand to achieve cost savings; generic prescribing will increase costs. Practice prescribing support software should be amended to ensure NACSYS brand is prescribed.

GREEN **ERTUGLIFLOZIN film-coated tablets (Steglatro® ▼)**

The Pan Mersey Area Prescribing Committee recommends the prescribing of ERTUGLIFLOZIN film-coated tablets (Steglatro® ▼) in a triple therapy regimen for treating type 2 diabetes in accordance with NICE TA583.

GREEN **SEMAGLUTIDE for type 2 diabetes**

Additional GLP-1 mimetic option. Cost is comparable to current formulary options.

GREEN **TRIMOVATE ointment for dermatoses**

Re-instatement in formulary following resolution of long-term supply issue.

AMBER INITIATED **TICAGRELOR tablets (Brilique®)**

The Pan Mersey Area Prescribing Committee recommends the prescribing of TICAGRELOR tablets (Brilique®), following specialist initiation, for the management of acute coronary syndromes in adults in accordance with NICE TA236 and for preventing atherothrombotic events after myocardial infarction in accordance with NICE TA420.

GP Support Resource: https://www.panmerseyapc.nhs.uk/media/2231/ticagrelor_support.pdf

AMBER RETAINED **ITRACONAZOLE for allergic bronchopulmonary aspergillosis**

The Pan Mersey Area Prescribing Committee recommends the prescribing of ITRACONAZOLE, for allergic bronchopulmonary aspergillosis.

AMBER RETAINED **CABERGOLINE for Parkinson's disease**

Addition of 1mg and 2mg tablets. Cost saving compared to use of 500microgram tablets.

AMBER INITIATED **ACICLOVIR eye ointment for Herpes simplex eye infection**

Removal from formulary – discontinued. Ganciclovir eye gel alternative formulary option (not recommended in pregnancy).

AMBER INITIATED **OMEGA-3 FATTY ACIDS for prevention of pancreatitis in hypertriglyceridaemia**

Re-instatement in formulary of omega-3 fatty acids for hypertriglyceridaemia (>10mmol/L) for prevention of pancreatitis, in addition / instead of statins and fibrates where these are ineffective/not tolerated.

AMBER INITIATED **STRONTIUM RANELATE for osteoporosis**

Now commercially available following previous discontinuation. Annual cost per patient £650 but minimal anticipated cost impact due to low patient numbers.

AMBER RECOMMENDED **LATANOPROST and TIMOLOL eye drops (Fixapost) for glaucoma**

Less costly preservative-free prostanoid agonist + beta-blocker combination eye drop option.

RED **TOLVAPTAN tablets (Samsca®) for the treatment of hyponatraemia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH)**

The Pan Mersey Area Prescribing Committee recommends the prescribing of TOLVAPTAN tablets (Samsca®), by specialists only, for the treatment of hyponatraemia secondary to SIADH due to any cause.

RED **MEXILETINE (Namuscla) for non – dystrophic myotonia**

Clarification that the Namuscla formulation is commissioned by NHS England, and that unlicensed mexiletine

formulation will continue to be prescribed for ventricular arrhythmias, as Namuscla is clinically unsuitable.

RED RITUXIMAB (Truxima® ▼, Rixathon® ▼) for immune (idiopathic) thrombocytopenic purpura

The Pan Mersey Area Prescribing Committee recommends the prescribing of rituximab by specialists only, for immune (idiopathic) thrombocytopenic purpura before romiplostin and eltrombopag.

RED CERTOLIZUMAB PEGOL solution for injection (Cimzia®) for Plaque Psoriasis

The Pan Mersey Area Prescribing Committee recommends the prescribing of CERTOLIZUMAB PEGOL solution for injection (Cimzia® ▼), by specialists only, for moderate to severe plaque psoriasis in accordance with NICE TA574.

RED TILDRAKIZUMAB solution for injection (Ilumetri® ▼) for moderate to severe plaque psoriasis

The Pan Mersey Area Prescribing Committee recommends the prescribing of TILDRAKIZUMAB solution for injection (Ilumetri® ▼), by specialists only, for moderate to severe plaque psoriasis in accordance with NICE TA575.

RED PSORIASIS in adults, sequential use of biological agents

The Pan Mersey Area Prescribing Committee recommends the sequential use of biological agents, adalimumab, brodalumab, certolizumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab, in the management of psoriasis according to the agreed flowchart.

GREY ALIROCUMAB solution for injection (Praluent® ▼) for reduction of cardiovascular risk in adults with established atherosclerotic cardiovascular disease

The Pan Mersey Area Prescribing Committee does not currently recommend the prescribing of ALIROCUMAB solution for injection (Praluent® ▼) for reduction of cardiovascular risk in adults with established atherosclerotic cardiovascular disease.

GREY PRASTERONE pessaries (Intrarosa® ▼) for vulvar and vaginal atrophy

The Pan Mersey Area Prescribing Committee does not currently recommend the prescribing of PRASTERONE pessaries (Intrarosa® ▼) for the treatment of vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms.

GREY SODIUM ZIRCONIUM CYCLOSILICATE powder for oral suspension (Lokelma® ▼) for treating hyperkalaemia

The Pan Mersey Area Prescribing Committee does not currently recommend the prescribing of SODIUM ZIRCONIUM CYCLOSILICATE powder for oral suspension (Lokelma® ▼) for treating hyperkalaemia.

GREY RISANKIZUMAB solution for injection (Skyrizi® ▼) for moderate to severe plaque psoriasis

The Pan Mersey Area Prescribing Committee does not currently recommend the prescribing of RISANKIZUMAB solution for injection (Skyrizi® ▼) for moderate to severe plaque psoriasis.

GREY BUDESONIDE (Jorvaza) for eosinophilic oesophagitis

Clarification of removal of off-label budesonide nebules formulary entry (RAG designation Red). May continue to be prescribed by secondary care pending outcome of NICE appraisal of Jorvaza formulation (currently designated Grey) specifically licensed for this indication.

GUIDELINES

Asthma - primary care paediatric guidelines

Updated versions of current guidelines with simplified preferred choice inhaler options. Based on BTS asthma guidelines.

- **Children less than 5 years old**
- **Children 5 years old and over**

Headache pathway

Update of current guideline incorporating new RAG designation for valproate in women of child-bearing potential - **AMBER RETAINED** (not routinely recommended in headache prevention in women of child-bearing potential).

Testosterone for men with secondary androgen deficiency, guidance for primary care prescribing

Guidance on symptoms and testosterone levels suggesting where referral to specialist may be appropriate, designation of testosterone RAG, and prescribing guidance for primary care clinicians.

SAFETY

INSULIN: reducing errors in prescribing and administration

Single document replaces previous safety advice for high strength insulin, biosimilar insulin, prescription sheet and record chart.

VALPROATE: safe prescribing and dispensing to girls of any age and women of childbearing potential

Minor update for noting. Updated link to new risk assessment form. Wording changes to reflect specialist role in assessing the need for contraception.

Medicines Management Work Plan 2019/20

During September and October 2019 NHS Halton CCG Medicines Management Team will be doing the following pieces of work:

- **Medication Reviews –** The CCG Medicines Management Pharmacists will be focussing on medication reviews for patients living with frailty and at risks of falls prioritising patients most at risk.
- **Practice Medicine Co-ordinator (PMC) Reviews** – The PMCs will be doing the following reviews:

  September:
  - **Duraphat® Toothpaste –** Discontinuation of Duraphat® Toothpaste as for dental prescribing only.
  - **Rubefacients –** Discontinuation of rubefacients in line with Pan Mersey BLACK RAG status.
  - **Branded Eye Drops –** Switch of branded eye drops (Azopt®, Cosopt®, Xalatan®, Xalacom®, Trusopt®) to generic equivalents.
  - **Hydrocortisone 10mg Tablets –** Switch of generic hydrocortisone 10mg tablets to the branded generic Hydventia®.
  - **High Risk Drug Monitoring Lithium –** audit of patients prescribed Lithium to check that the recommended monitoring has been completed and lithium is prescribed by brand.

  October:
  - **High Risk Drug Monitoring Carbimazole** – review of females of child bearing potential prescribed carbimazole and their current contraception for highlighting to prescribers in line with the MHRA Drug

safety Update (https://www.gov.uk/drug-safety-update/carbimazole-increased-risk-of-congenital-malformations-strengthened-advice-on-contraception)

- **Omacor® -** Stopping Omacor in patients prescribed for inappropriate indications in line with Pan Mersey BLACK RAG status.
- **Branded Triptans -** Switch of branded triptans to generic equivalents.
- **Dementia Drugs** – Switch of galantamine capsules and rivastigmine patches to branded generics Gazylan XL® and Alzest®.

Hot Topic – Safety Alerts

GP PRACTICE REGISTRATION FOR CAS ALERTS

In support of improving patient safety alerting system resilience for General Practice, there are new contractual requirements for practices. From 1 October 2019, MHRA will send CAS alerts directly to GP practices taking over existing local patient safety CAS alert email cascade mechanisms currently in place.
All GP practices in England are required to register to receive CAS alerts directly from the MHRA by accessing this portal: https://www.cas.mhra.gov.uk/Register.aspx

Until 1 October, NHS England and NHS Improvement regional teams will continue to issue CAS alerts to general practice.

NIGEL'S SURGERY 91: PATIENT SAFETY ALERTS

CQC recommends practices should have a system in place to ensure that they are receiving, disseminating and acting upon all alerts and information relevant to general practice.
Practices should:

- Consider who should receive alerts and information within the practice.
- Make sure there are effective processes in place to act upon alerts received.
- Arrange cover for annual leave or staff absences.

For example, a practice could keep a log of alerts received and document action taken in response to these. There should be clinical oversight of the process.
Practices need to ensure they monitor updates and alerts and act upon these in a timely manner. They need:

- Systems in place to identify, recall and follow-up affected patients and to follow-up on these where required.
- A process to recall a medicine or device.
- To incorporate prescribing advice into routine clinical practice, in the same way as any other prescribing guidance. This could be through medication reviews or as part of the practice audit programme, for example.
  https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-91-patient-safety-alerts

The Medicines Management Team will also highlight any medicines related safety advice to the Practice Prescribing Lead and the Practice Medicines co-ordinator (PMC) for consideration. The Medicines Management Team is happy to provide practice support to ensure the actions of an alert are completed.

Driver and Vehicle Licensing Agency (DVLA): Flash Glucose Monitoring systems (FGM) and Real Time Continuous Glucose Monitoring systems (RT-CGM) update.

The DVLA has updated their guidance on the monitoring requirements when driving with diabetes.
Group 1 drivers may now use flash glucose monitoring (FGM) for driving, however they must get a confirmatory finger prick blood glucose level in certain circumstances (see below).
Group 2 drivers must continue to monitor finger prick capillary blood glucose levels for driving. Flash glucose monitoring systems are not legally permitted for Group 2 driving.

Group 1: Car and Motorcycle

- FGM (e.g. FreeStyle Libre) and RT-CGM may be used for monitoring glucose at times relevant to driving Group 1 vehicles.
- Users of these systems must carry finger prick capillary glucose testing equipment for driving purposes as there are times when a confirmatory finger prick blood glucose level is required. For example:
  - When the glucose level is 4.0 mmol/L or below.
  - When symptoms of hypoglycaemia are being experienced.
  - When the glucose monitoring system gives a reading that is not consistent with the symptoms being experienced (e.g. symptoms of hypoglycaemia and the system reading does not indicate this).

Reminder of glucose self-monitoring requirements for licensing of insulin-treated Group 1 drivers:

- Glucose testing no more than 2 hours before the start of the first journey.

And

- Every 2 hours after driving has started.
- A maximum of 2 hours should pass between the pre-driving glucose test and the first glucose check performed after driving has started.
- Applicants will be asked to sign an undertaking to comply with the directions of the healthcare professionals treating their diabetes and to report any significant change in their condition to the DVLA immediately.

More frequent self-monitoring may be required with any greater risk of hypoglycaemia (physical activity, altered meal routine).

Group 2: Bus and Lorry

- FGM (e.g. FreeStyle Libre) and RT-CGM interstitial fluid glucose monitoring systems are not permitted for the purposes of Group 2 driving and licensing.
- Insulin-treated group 2 drivers who use these devices must continue to monitor finger prick capillary blood glucose levels with the regularity defined below.
  - Regular blood glucose testing – at least twice daily including on days when not driving.

  And
  - No more than 2 hours before the start of the first journey.

  And
  - Every 2 hours after driving has started.

A maximum of 2 hours should pass between the pre-driving glucose test and the first glucose check performed after driving has started.

DVLA. Published 11th March 2016. Last updated 14th February 2019. Diabetes Mellitus: Assessing fitness to drive. (Online) Available at https://www.gov.uk/guidance/diabetes-mellitus-assessing-fitness-to-drive Accessed 4th July 2019.

Safety

HORMONE REPLACEMENT THERAPY (HRT): FURTHER INFORMATION ON THE KNOWN INCREASED RISK OF BREAST CANCER WITH HRT AND ITS PERSISTENCE AFTER STOPPING

New data has confirmed that the risk of breast cancer is increased during use of all types of HRT, except vaginal estrogens, and has also shown that an excess risk of breast cancer persists for longer after stopping HRT than previously thought.
Prescribers of HRT should discuss the updated total risk with women using HRT at their next routine appointment.

Advice for healthcare professionals:

- A new meta-analysis of more than 100,000 women with breast cancer has shown that some excess risk of breast cancer with systemic HRT persists for more than 10 years after stopping; the total increased risk of breast cancer associated with HRT is therefore higher than previous estimates.
- Prescribers of HRT should inform women who use or are considering starting HRT of the new information about breast cancer risk at their next routine appointment.
- Only prescribe HRT to relieve post-menopausal symptoms that are adversely affecting quality of life and regularly review patients using HRT to ensure it is used for the shortest time and at the lowest dose.
- Remind current and past HRT users to be vigilant for signs of breast cancer and encourage them to attend for breast screening when invited.

Please see the full alert for further important information on key findings from the study, a table summarising numbers of HRT-related breast cancers estimated from the new study and information/resources that can be used when counselling patients about the updated information on risk of breast cancer with HRT.

https://www.gov.uk/drug-safety-update/hormone-replacement-therapy-hrt-further-information-on-the-known-increased-risk-of-breast-cancer-with-hrt-and-its-persistence-after-stopping

DIRECT-ACTING ORAL ANTICOAGULANTS (DOACS): INCREASED RISK OF RECURRENT THROMBOTIC EVENTS IN PATIENTS WITH ANTIPHOSPHOLIPID SYNDROME

MHRA advises that DOACs are not recommended in patients with antiphospholipid syndrome, particularly high-risk patients (those who test positive for all 3 antiphospholipid tests — lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2 glycoprotein I antibodies).
Healthcare professionals are advised to review whether continued treatment with a DOAC is appropriate for patients diagnosed with antiphospholipid syndrome, particularly high-risk patients, and consider switching to a vitamin K antagonist such as warfarin.

https://www.gov.uk/drug-safety-update/direct-acting-oral-anticoagulants-doacs-increased-risk-of-recurrent-thrombotic-events-in-patients-with-antiphospholipid-syndrome

GLP-1 RECEPTOR AGONISTS: REPORTS OF DIABETIC KETOACIDOSIS WHEN CONCOMITANT INSULIN WAS RAPIDLY REDUCED OR DISCONTINUED

Serious and life threatening cases of diabetic ketoacidosis have been reported in patients with type 2 diabetes on a combination of a GLP-1 receptor agonist (Exenatide, Liraglutide, and Dulaglutide) and insulin who had doses of concomitant insulin rapidly reduced or discontinued. It is advised that blood glucose self-monitoring is necessary when adjusting the dose of insulin, particularly when GLP-1 receptor agonist therapy is initiated, and insulin is

reduced. Any insulin dose reduction should be done in a stepwise manner. Healthcare professionals should discuss with patients the risk factors for and signs and symptoms of diabetic ketoacidosis and advise them to seek immediate medical advice if these develop.

https://www.gov.uk/drug-safety-update/glp-1-receptor-agonists-reports-of-diabetic-ketoacidosis-when-concomitant-insulin-was-rapidly-reduced-or-discontinued

ORAL RETINOID MEDICINES▼: REVISED AND SIMPLIFIED PREGNANCY PREVENTION EDUCATIONAL MATERIALS FOR HEALTHCARE PROFESSIONALS AND WOMEN

New prescriber checklists, patient reminder cards, and pharmacy checklists are available to support Pregnancy Prevention Programme in women on Acitretin, Alitretinoin and isotretinoin. Advice about risk of neuropsychiatric reactions has been made consistent for all oral retinoids.

https://www.gov.uk/drug-safety-update/oral-retinoid-medicines-revised-and-simplified-pregnancy-prevention-educational-materials-for-healthcare-professionals-and-women

RIVAROXABAN (XARELTO▼): REMINDER THAT 15 MG AND 20 MG TABLETS SHOULD BE TAKEN WITH FOOD

Advice for healthcare professionals:

- Remind patients to take rivaroxaban 15 mg or 20 mg tablets with food.
- For patients who have difficulty swallowing, tablets can be crushed and mixed with water or apple puree immediately before taking; this mixture should be immediately followed by food.
- Rivaroxaban 2.5 mg and 10 mg tablets can be taken with or without food.

https://www.gov.uk/drug-safety-update/rivaroxaban-xarelto-reminder-that-15-mg-and-20-mg-tablets-should-be-taken-with-food

FEBUXOSTAT (ADENURIC): INCREASED RISK OF CARDIOVASCULAR DEATH AND ALL-CAUSE MORTALITY IN CLINICAL TRIAL IN PATIENTS WITH A HISTORY OF MAJOR CARDIOVASCULAR DISEASE

Advice for healthcare professionals:

- Avoid treatment with Febuxostat in patients with pre-existing major cardiovascular disease (for example, myocardial infarction, stroke, or unstable angina); unless no other therapy options are appropriate.
- Clinical guidelines for gout recommend treatment with Febuxostat only when allopurinol is not tolerated or contraindicated.

https://www.gov.uk/drug-safety-update/febuxostat-adenuric-increased-risk-of-cardiovascular-death-and-all-cause-mortality-in-clinical-trial-in-patients-with-a-history-of-major-cardiovascular-disease

INSULIN PATIENT SAFETY INCIDENT

We would like to highlight the importance of adherence to Pan Mersey prescribing recommendations of Amber Initiation when prescribing is transferred to a primary care prescriber for ALL insulin prescribing .

A patient's insulin therapy was changed from Insulin vial plus syringe with needles to a high strength insulin pre-filled pen plus pen needle following a review with the specialist diabetes team within secondary care.
A written request was sent from the Trust to the GP to initiate the new insulin regimen. The new pen needles were not entered onto the patient's medication list in the GP practice and were not dispensed with the new insulin. The patient subsequently used the previous syringe and needle device to draw and administer insulin out of the new insulin pre-filled pen. The patient was found unconscious the following day and admitted to hospital following a hypoglycaemic attack. Fortunately the patient was discharged the following day.
Following a significant event analysis carried out by the Practice, a key issue identified was non-adherence by both the Trust and the Primary Care Prescriber to Amber Initiation RAG status for all insulin.
Where insulin is initiated in secondary care, Pan Mersey formulary recommends the following:

Transfer of insulin prescribing to primary care prescriber

Before requesting that Primary Care takes over prescribing of newly initiated insulin the specialist team must be assured that the patient is willing, competent and trained to:

- Administer the insulin (or District Nurse arranged).
- If and when required amend the dose of the insulin, either with the support of their diabetes HCP or independently.

During this time prior to requesting Primary Care take over prescribing, the specialist team must maintain clinical responsibility, review the patient (either face to face or by telephone) and prescribe the insulin and administration devices for:

- A minimum of 4 weeks supply.

OR

- A supply length that allows enough time for the patient to be reviewed by the specialist team, whichever of the above is the longer.

A copy of the final review must be sent to the primary care prescriber with the request for transfer of prescribing. Please ensure all insulin prescribing is in line with safety recommendations set out in Pan Mersey formulary. Please also refer to Pan Mersey safety statement, 'INSULIN: reducing errors in prescribing and administration' for additional advice.
https://www.panmerseyapc.nhs.uk/media/2253/insulin.pdf?UNLID=101474697720197301584

Practices are encouraged to report incidents of non-adherence to Pan Mersey recommendations for insulin prescribing via the Pan Mersey interface form available on the APC website.

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