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Area Prescribing Committee

NEW MEDICINES

RED GALCANEZUMAB injection (Emgality® ▼) for prevention of migraine

Galcanezumab is the second biologic agent to be recommended by NICE for preventing migraine. PBR excluded high-cost drug, for specialist use only. It is an alternative treatment option in the pathway, alongside fremanezumab.

RED UPADACITINIB prolonged release tablets (RINVOQ® ▼) for treating severe rheumatoid arthritis

Upadacitinib is another oral biologic treatment option, recommended by NICE for treating severe rheumatoid arthritis. PBR excluded high-cost drug, for specialist use only.

RED LIRAGLUTIDE injection (Saxenda®) for managing overweight and obesity

Saxenda is recommended by NICE for managing overweight and obesity for adults who meet specific weight criteria and have a high risk of cardiovascular disease. It needs to be prescribed in secondary care by a specialist MDT tier 3 weight management service in order to be able to access the PAS discount.

GREY FILGOTINIB tablets (Jyseleca® ▼) for rheumatoid arthritis

Not recommended until NICE TA published

GREY GUSELKUMAB injection (Tremfya® ▼) for psoriatic arthritis

Not recommended until NICE TA published.

GREY BARICITINIB film-coated tablets (Olumiant® ▼) for atopic dermatitis

Not recommended until NICE TA published.

GREY DAPAGLIFLOZIN tablets (Forxiga®) for heart failure with reduced ejection fraction Not recommended until NICE TA published.

AMBER INITIATED SACUBITRIL/VALSARTAN film-coated tablets (Entresto® ▼) for chronic heart failure

Routine review of existing amber initiated statement, for inclusion on the static list. Key changes are the removal of the requirement for patients to be on stable optimised ACE inhibitor/Angiotensin-II receptor inhibitor for 3 months before sacubitril/valsartan is commenced and to clarify the definition of 'specialist'. Cost impact unclear as uptake locally has been significantly less than estimated by NICE at the time the TA was published.

Supporting NWCSCN documents have also been updated and are hyperlinked within the policy statement.

FORMULARY AND GUIDELINES

AMBER INITIATED Flash glucose monitoring (FreeStyle Libre®)

Addition of people with diabetes and a learning disability who use insulin to treat their diabetes to the statement, in line with [NHSE recommendation](#).

GREEN Management of Chronic Constipation in Adult Patients in Primary Care

Addition of naldemedine for opioid-induced constipation to current guideline as per [NICE TA651](#).

Vitamin B12 deficiency in adults

New guideline to address need for oral dosing instead of hydroxocobalamin injection during pandemic, and to promote self-care for prevention of dietary insufficiency. Includes use of newly licensed cyanocobalamin 1mg tablets.

GREEN Addition of cyanocobalamin 1mg tablets to formulary

TEMPORARY WITHDRAWAL Direct Oral Anticoagulants (DOAC) in venous thromboembolism - RAG designation, for suspected venous thromboembolism (VTE) within agreed local treatment pathway

The current Pan Mersey statement is no longer up to date with respect to NICE guidance and it is preferable to temporarily withdraw it pending review in line with NICE NG158

GREEN Vitamin D Deficiency in Adults guideline

Minor amendment to current guideline with information regarding vitamin D supplementation during COVID-19 pandemic.

AMBER RECOMMENDED Thick & Easy® for dysphagia in paediatrics

Established choice of thickener for dysphagia in paediatrics – added to formulary to bring it in line with current practice.

SHARED CARE

PURPLE Routine review of the existing shared care frameworks for adults and children which follow NICE NG87

[Atomoxetine shared care framework](#)

[Dexamfetamine shared care framework](#)

[Guanfacine shared care framework](#)

[Lisdexamfetamine shared care framework](#)

[Methylphenidate shared care framework](#)

PURPLE New shared care frameworks for children attending Alder Hey Hospital and Wirral University Hospital

[Atomoxetine for children shared care framework](#)

[Dexamfetamine for children shared care framework](#)

[Guanfacine for children shared care framework](#)

[Lisdexamfetamine for children shared care framework](#)

[Methylphenidate for children shared care framework](#)

PURPLE Lithium shared care framework

Updated monitoring guidance to clarify that this applies to the risk of arrhythmia and not cardiac function in general.

AMBER RETAINED Gonadorelin analogues prescribing support information

Routine review with minor updates plus updated GP letter.

AMBER RETAINED Degarelix prescribing support information

Routine review with minor updates plus updated GP letter.

During **April and May 2021**, the NHS Halton CCG Medicines Management Team will continue to support with the following COVID-19 related work:

- high-risk drug monitoring
- palliative care medication
- respiratory prescribing
- medicines support to care Homes.
- electronic Repeat Dispensing (eRD).
- medicines supply issues.
- medication support guidance.
- Vaccination Programme

The MMT will also be focussing on the following work plan projects:

- lipid Optimisation
- STOMP-STAMP
- COPD Rescue Packs
- opioids in Chronic Pain
- oral nutritional supplements

Practice Medicine Co-ordinator (PMC) Reviews

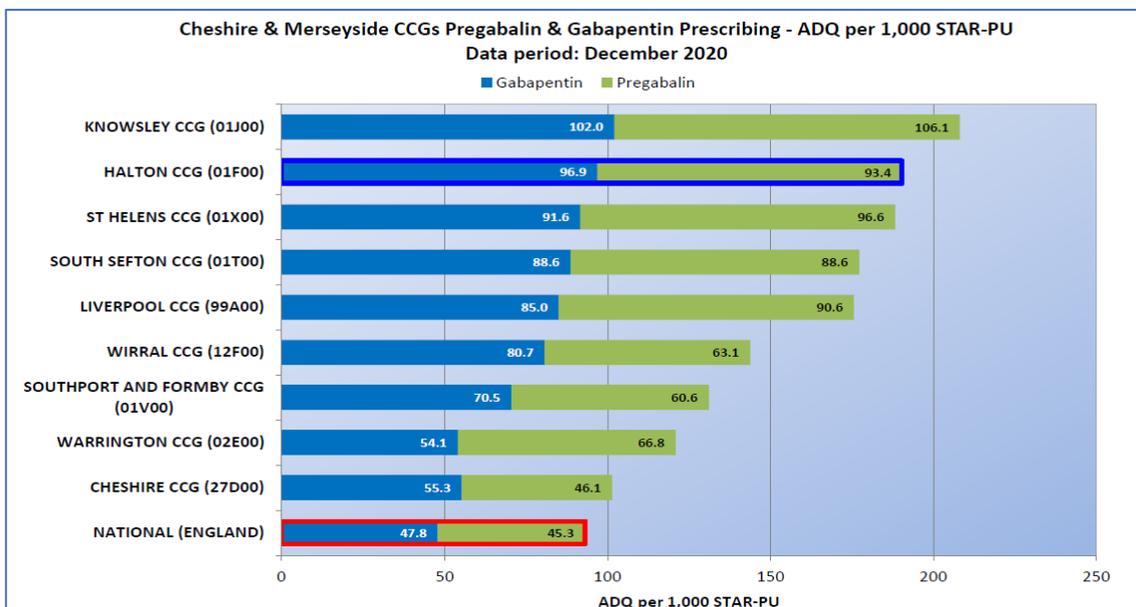
The PMCs will be doing the following reviews during April & May:

- Safety Reviews:
 - drug monitoring of theophylline
 - appropriate branding of liraglutide formulations
 - valproate in females
- New switches:
 - Yasmin[®]/Generic to Yacella[®] Switch
 - Alfuzosin MR 10mg tablets to Bezavar[®]
 - Hylo-Forte[®] Eye drops to Evolve[®]
- Mop ups of previous switches:
 - Fultium D3 to Invita D3 800iu Capsules
 - Diabetic Needles to BD Viva[®]
- Support with Communications for new Stoma Service (MARRS)

Hot Topic - Gabapentinoids- safety concerns and reports of severe respiratory depression

There appears to be growing evidence highlighting safety concerns associated with prescribing of gabapentinoids, namely pregabalin and gabapentin.

Locally, NHS Halton CCG have high prescribing volumes of both of these medicines and are identified as an outlier compared to National prescribing data.



A recent [MHRA Drug Safety Update](#) has highlighted the risk of severe respiratory depression when pregabalin is prescribed alone. This is in addition to the already established risk of respiratory depression, coma, and death when pregabalin is co-prescribed with other CNS depressants, particularly opioids. Studies show use of high doses of pregabalin (over 300mg a day) alongside opioid medicines to be particularly associated with an increased risk of opioid-related death.

A previous [MHRA safety alert](#) in 2017 has also highlighted a similar risk of respiratory depression when gabapentin is prescribed alone.

Of the cases highlighted in a recent European review of safety data, the risk of respiratory depression appeared to be of particular concern at the point of initiation or dose increase and the majority of cases were in elderly patients. The MHRA safety update for pregabalin provides the following recommendations:

Advice for healthcare professionals:

- pregabalin has been associated with reports of respiratory depression, in some cases **without** concomitant opioid treatment
- consider whether adjustments in dose or dosing regimen are necessary for patients at higher risk of respiratory depression, this includes people:
 - with compromised respiratory function, respiratory or neurological disease, or renal impairment
 - taking other CNS depressants (including opioid-containing medicines)
 - aged older than 65 years

Advice to give to patients and carers:

- some patients have experienced breathing difficulties when taking pregabalin – certain people may need a lower dose to reduce the risks of these issues
- contact your doctor if you notice new or increased trouble breathing or you experience shallow breathing after taking pregabalin; a noticeable change in breathing might be associated with sleepiness
- read the leaflet that comes with your medicine and talk to your doctor or pharmacist if you are worried about the other prescribed medicines you are taking with pregabalin.
- avoid drinking alcohol during pregabalin treatment

The risk of abuse and dependence associated with the prescribing of pregabalin, and gabapentin has also been identified, leading to the re-classification of these medications as Schedule 3 Controlled Drugs in April 2019.

The Medicines Management Team recommend review of prescribing of pregabalin and gabapentin at any opportunity. The team plan to support review of patients currently prescribed pregabalin by developing a search to identify the high-risk patients currently prescribed pregabalin with other identifiable risk factors. An Optimise Rx

message will also be available to highlight the risk of respiratory depression with these medicines at the point of initiation/re-authorisation.

Warfarin

Following concerns raised by clinicians during the coronavirus (COVID-19) pandemic, the MHRA have issued advice to healthcare professionals and patients regarding the safe use of warfarin and other anticoagulants. This advice has been endorsed by the Commission on Human Medicines (CHM).

Healthcare professionals are reminded that:

- Acute illness may exaggerate the effect of warfarin and necessitate a dose reduction; patients on warfarin or other vitamin K antagonists should therefore be asked to tell their GP or healthcare team if they have symptoms of, or confirmed, COVID-19 infection.
- Continued INR (international normalised ratio) monitoring is important in patients taking warfarin or other vitamin K antagonists if they have suspected or confirmed COVID-19 infection, so they can be clinically managed at an early stage to reduce the risk of bleeding.
- Both vitamin K antagonists and direct-acting oral anticoagulants (DOACs) may interact with other medicines and if a patient using these oral anticoagulants is also prescribed antibiotics or antivirals, follow advice in the product information for minimisation of risk of potential interactions – this includes INR monitoring in patients taking vitamin K antagonists who have recently started new medicines.
- If patients are switched from warfarin to a DOAC, warfarin treatment should be stopped before the DOACs is started to reduce the risk of over-anticoagulation and bleeding.
- Patients taking vitamin K antagonists should be reminded to carefully follow the instructions for use for anticoagulant medicines (including the patient information leaflet) and to tell their GP or healthcare team if they:
 - Are otherwise unwell with sickness or diarrhoea or have lost their appetite.
 - Are taking any new medicines or supplements.
 - Have changed their diet, smoking habits, or alcohol consumption.
 - Are unable to attend their next scheduled blood test for any reason, including because they feel unwell.

<https://www.gov.uk/government/publications/warfarin-and-other-anticoagulants-monitoring-of-patients-during-the-covid-19-pandemic/warfarin-and-other-anticoagulants-monitoring-of-patients-during-the-covid-19-pandemic>

Safety

The Medicines Management Team would like to highlight some of the recent drug safety updates relevant to Primary Care:

COVID-19 VACCINES AND MEDICINES UPDATES FROM THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

[COVID-19 vaccines and medicines: updates for March 2021 - GOV.UK \(www.gov.uk\)](#)

From: Medicines and Healthcare products Regulatory Agency Published: 24 March 2021

[COVID-19 vaccines and medicines: updates for February 2021 - GOV.UK \(www.gov.uk\)](#)

From: Medicines and Healthcare products Regulatory Agency Published: 18 February 2021

[COVID-19 vaccines \(Pfizer/BioNTech and COVID-19 Vaccine AstraZeneca\): current advice - GOV.UK \(www.gov.uk\)](#)

From: Medicines and Healthcare products Regulatory Agency Published: 7 January 2021

SOPROBEC 200 MICROGRAMS INHALER - COLOUR CHANGE

Soprobec (beclometasone dipropionate) 200 micrograms per actuation pressurised inhalation solution – change in the colour of plastic actuator and protective cap

Soprobec 200 micrograms inhaler, with a light brown actuator with cream dust cap, will soon be replaced by a pink actuator with red dust cap.

The changes are to avoid confusion with a similar product with a lower strength of beclomethasone dipropionate. The outer carton will contain the message 'New actuator colour':



SYSTEMIC AND INHALED FLUOROQUINOLONES: SMALL RISK OF HEART VALVE REGURGITATION; CONSIDER OTHER THERAPEUTIC OPTIONS FIRST IN PATIENTS AT RISK

Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk for heart valve regurgitation (incompetence).

[Systemic and inhaled fluoroquinolones: small risk of heart valve regurgitation; consider other therapeutic options first in patients at risk - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

ERYTHROMYCIN: CAUTION REQUIRED DUE TO CARDIAC RISKS (QT INTERVAL PROLONGATION); DRUG INTERACTION WITH RIVAROXABAN

Erythromycin has been associated with events secondary to QT interval prolongation such as cardiac arrest and ventricular fibrillation. Erythromycin should not be given to patients with a history of QT interval prolongation or ventricular cardiac arrhythmia, including torsades de pointes, or patients with electrolyte disturbances. A potential drug interaction between rivaroxaban and erythromycin resulting in increased risk of bleeding has also been identified.

[Erythromycin: caution required due to cardiac risks \(QT interval prolongation\); drug interaction with rivaroxaban - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

SSRI/SNRI ANTIDEPRESSANT MEDICINES: SMALL INCREASED RISK OF POSTPARTUM HAEMORRHAGE WHEN USED IN THE MONTH BEFORE DELIVERY

SSRIs and SNRIs are known to increase bleeding risks due to their effect on platelet function. Data from observational studies suggest that the use of SSRI/SNRI antidepressants during the month before delivery may result in a small increased risk of postpartum haemorrhage. Prescribers should consider this risk in the context of an individual patient's bleeding and thrombotic risk assessment during the peripartum period and the benefits of antidepressants for the patient's mental health during this time.

[SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

Other Online resources of note -

[COVID-19 vaccines \(Pfizer/BioNTech and COVID-19 Vaccine AstraZeneca\): current advice - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

Antimicrobial Update: March 2021

COVID-19 THERAPEUTIC ALERT: 28TH JANUARY 2021

Antimicrobials (azithromycin and doxycycline) Not Beneficial in the Management of COVID-19 (SARS-CoV-2) Positive Patients

- Clinical trials have concluded that there is no clinically meaningful benefit of administering either azithromycin or doxycycline to patients being treated at home in the early stages of covid-19.
- Antimicrobials should NOT be used in the primary management of COVID-19 infection unless there are other licensed indications for which its use remains appropriate.
- Continue to refer to [NICE COVID-19 rapid guideline \(NG165\)](#): managing suspected or confirmed pneumonia in adults in the community to help differentiate between viral and bacterial pneumonia
- Inappropriate antibiotic use may reduce their availability, and indiscriminate use may lead to Clostridioides difficile infection and antimicrobial resistance.

TIPS TO SUPPORT ANTIMICROBIAL STEWARDSHIP DURING REMOTE CONSULTATION:

- Refer to [GMC guidance](#) to decide if remote consultation is appropriate
- Utilise [Pan Mersey anti-infective guidance](#) to guide empirical choice of antibiotics
- Utilise clinical scoring tools such as [feverPAIN](#) to support clinical judgement as to whether or not an immediate antibiotic is required
- Utilise back up prescriptions for antibiotics, particularly for upper respiratory tract infections and uncomplicated urinary tract infections in lower risk individuals
- Utilise communication via 'AccuRx' to support decision making and facilitate the sharing of information with patients, for example:
 - Allowing patients to send images to aid diagnosis
 - Sharing mobile friendly version of TARGET 'Treating Your Infection' patient information leaflets

TARGET TOOLKIT WEBINAR: COMMON INFECTIONS IN EXTRAORDINARY TIMES – DECISION POINTS FOR REMOTE MANAGEMENT

This 30-minute presentation looks into the remote consultation during COVID-19 and aims to help prescribers identify key decision points for remote management of common infections e.g., ENT, Urinary, Cough, COVID-19, and insect bites. (November 2020).

[NOW AVAILABLE TO VIEW ONLINE](#)

PAN MERSEY ANTI-INFECTIVE GUIDELINES: MANAGING COMMON INFECTION IN ADULTS

All sections have now been updated and are available to access on the [Pan Mersey website](#).

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