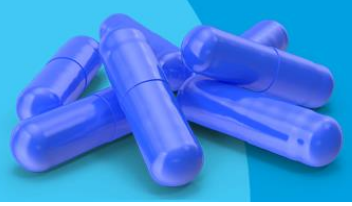
Medicines Management newsletter

Issue 14– February 2019

Halton Clinical Commissioning Group



Area Prescribing Committee

RECOMMENDATIONS SPECIFICALLY RELEVANT TO PRIMARY CARE

RED METHADONE tablets for Pain (Physeptone®)

Halton prescribers should be aware that whilst the Pan Mersey APC committee proposed this as amber retained, based on feedback from local clinicians NHS Halton CCG Medicines Management Working Group recommended that this be approved as RED. This has been approved by NHS Halton CCG Quality Committee.

As this is approved as RED in the Halton area we would expect prescribing to remain with the specialist service and primary care should not be asked to pick up prescribing once initiated.

For Halton the **RED** status is stipulated in the formulary entry.

http://formulary.panmerseyapc.nhs.uk/chaptersSubDetails.asp?FormularySectionID=4&SubSectionRef=04.07.02&SubSectionID=A100&drugmatch=5702#5702

DEMENTIA: behavioural and psychological symptoms (BPSD), use of antipsychotics

The Pan Mersey Area Prescribing Committee recommends that antipsychotics prescribed for BPSD should be initiated by a dementia specialist and reviewed in accordance with NICE/SCIE guidelines.

GENERALISED ANXIETY DISORDER in adults - Updated Pharmacological treatment pathway.

NEUROPATHIC PAIN, pharmacological management in non-specialist settings - This guideline is for use in primary care for initial management, not in specialist pain service settings. This now includes a link to the new **BLACK** APC statement for lidocaine plasters. Details of the **BLACK** lidocaine plasters statement are available here.

GENITAL TRACT INFECTIONS - Chlamydia update

Doxycycline* is now recommended first line, apart from in pregnancy (see below link for full details of treatment in pregnancy). Emerging co-infection with macrolide resistant Mycoplasma genitalium is likely due to widespread use of azithromycin.

* Avoid in pregnancy

For full details of dosage regimens, duration of treatment and treatment in pregnancy please refer to the full formulary entry:
http://formulary.panmerseyapc.nhs.uk/chaptersSubDetails.asp?FormularySectionID=27&SubSectionRef=27.11&SubSectionID=A100&drugmatch=5571#5571

FORMULARY

RED **TERIPARATIDE for osteoporosis in males** - This is now commissioned by NHS England for osteoporosis in males and CCGs will no longer fund (PBR excluded drug).

AMBER RECOMMENDED **Cortiment® (budesonide m/r) for Crohn's disease** - This now an equivalent option to Clipper® (beclomethasone m/r).

AMBER RECOMMENDED **Pilocarpine tablets for dry mouth caused by irradiation for head & neck cancers and Sjogren's syndrome.** Change in RAG rating from Red to Amber Recommended to reflect that almost all the prescribing is in primary care.

GREEN **Evolve HA® eye drops (sodium hyaluronate 0.2% eye drops) for Dry eyes** - Additional lower-cost brand to be 1st-line option. (Evolve HA® £5.99, Hyloforte® £9.50 per 10ml)

GREEN **GABAPENTIN AND PREGABALIN for restless legs syndrome** - Additional RAG designation clarifying as suitable for initiation in primary care for this indication, 2nd line option to dopaminergic agents (off-label indication). Minimal cost implication anticipated.

GREEN **ITRACONAZOLE for Chronic pulmonary aspergillosis** - This indication is commissioned by NHS England.

SHARED CARE

PURPLE **DMD Shared Care Frameworks** - Clarification of the monitoring recommendations.
https://www.panmerseyapc.nhs.uk/shared-care/

PRESCRIBING SUPPORT INFORMATION

AMBER INITIATED **Dementia** - Updated document at routine review-by-date – minimal changes to reflect new NICE guidance (NG97).

https://www.panmerseyapc.nhs.uk/media/2091/dementia.pdf

ANTIMICROBIAL PRESCRIBING

Fungal infections

http://formulary.panmerseyapc.nhs.uk/chaptersSubDetails.asp?FormularySectionID=27&SubSectionRef=27.13&SubSectionID=A100

Medicines Management Work Plan 2018/19

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

- **Pregabalin and Gabapentin CD classification** – The MM Team will be supporting practices with the changes that are required to the prescribing of pregabalin and gabapentin as a result of their reclassification as Schedule 3 controlled drugs from 1st April 2019, as detailed in the Hot Topic.
- **Lithium Review –** a review of the prescribing of lithium against local shared care arrangements and documentation, for feedback and to agree actions with local mental health trust.
- **Valproate Review –** a re-audit of the prescribing of valproate in females of child bearing age for compliance with the Pregnancy Prevention Programme for feedback to GP practices and local trusts.
- **Freestyle Libre Monitor Review –** a review of the prescribing of Freestyle Libre sensors against local guidance and documentation, for feedback at practice and CCG level and to agree actions with local diabetes team.

Hot Topic – Reclassification of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs

From 1 April 2019, gabapentin and pregabalin will be reclassified as Schedule 3 controlled drugs under the Misuse of Drugs Regulations 2001, and Class C of the Misuse of Drugs Act 1971.

This means that in addition to the normal prescription requirements for prescription only medicines (as required by the Human Medicines Regulations 2012), prescriptions for Schedule 3 controlled drugs must also contain the following (as outlined in the Misuse of Drugs Regulations 2001):

- **Signature** - The prescription needs to be signed by the prescriber with their usual signature. This must be in **INK.**
- **Dose** (which must be clearly defined; 'as directed' is not acceptable).
- **Date** - Controlled Drugs prescriptions are valid for 28 days after the appropriate date on the prescription. The appropriate date is either the signature date or any other date indicated on the prescription (by the prescriber) as a date before which the drug should not be supplied – whichever is the later.

EXAMPLES OF DOSES THAT ARE LEGALLY ACCEPTABLE (NB: LEGAL ACCEPTABILITY DOES NOT AUTOMATICALLY INDICATE CLINICAL APPROPRIATENESS)

- One as directed
- Two when required
- One PRN
- Three ampoules to be given as directed (better still – three ampoules to be given over 24 hours as directed)
- One to two when required

- **Address of the prescriber** - The address of the prescriber must be included on the prescription and must be within the UK.
- **Formulation** - must be stated; the abbreviation 'tabs' and 'caps' are acceptable.
- **Strength** (where appropriate).
- **Total quantity** or dosage units of the preparation **must be in both words and figures.**

Additionally the following considerations must be taken into account:

- It is strongly recommended that quantities do not exceed 30 days' supply. It is recommended that quantities are kept to 28 rather than 30 for regular items to help keep in line with other items on repeat.
- Currently in the Halton area controlled drug prescriptions in schedule 2 and 3 cannot be sent via EPS and practices need to have procedures in place to ensure EPS patients receive their CD hard copy prescriptions.
- A clear audit trail should be in place for the safe handing over of all CD prescriptions to the correct patient or representative.
- Schedule 3 CDs cannot be prescribed on repeat dispensing prescription.
- **Emergency supply is not permitted.** There must be a valid controlled drug prescription to obtain supplies from a pharmacy.

Please note all other normal prescription requirements are still needed for a legal supply of medication to occur.

In preparation for this EMIS have already categorised pregabalin and gabapentin as controlled drugs on the practice systems, as a result this means that prescriptions for pregabalin and gabapentin can no longer be sent by EPS with immediate effect. This means that, in a similar way to other CD prescriptions, practices need to have procedures in place to ensure EPS patients receive their hard copy prescriptions for pregabalin and gabapentin.

All relevant practice staff will need to be made aware that all requirements detailed in the practice's CD standard operating procedures will apply to pregabalin and gabapentin prescriptions from 1st April 2019.

It is recommended that GP practices review any prescriptions for pregabalin and gabapentin to check they meet the requirements above, in particular:

- Amend any dosage that is written as 'as directed' or includes an historic dose titration to the current dosage the patient is on. Specific dose titrations are acceptable but it will be necessary to update them as the patient's dose stabilises so it is clear what the current dosage is.
- Ensure quantity is for a maximum of 28 days based on current dosage.
- Stop repeat dispensing for gabapentin and pregabalin as early as possible before 1 April 2019 and put transition arrangements in place for patients.
- Inform all patients currently taking pregabalin and gabapentin about the impact this change will have on their prescriptions. Ask them to ensure they request any prescriptions in plenty of time, to help the NHS to manage the transition process.

The Medicines Management Team will be supporting practices with this work in February and March 2019.

It is recommended that pharmacies ensure that your pharmacy team is aware of the change in the law and understands the new process with regard to prescriptions for these drugs and communicate about this change to patients.

Safety

TAPENTADOL (PALEXIA): RISK OF SEIZURES AND REPORTS OF SEROTONIN SYNDROME WHEN CO-ADMINISTERED WITH OTHER MEDICINES

MHRA have highlighted an increased seizure risk with Tapentadol in patients taking other medicines that lower seizure threshold, for example, antidepressants and antipsychotics.

Serotonin syndrome has also been reported when tapentadol is used in combination with serotoninergic antidepressants.

Advice for Healthcare Professionals:

- As for all opioid medicines, tapentadol can induce seizures.
- Tapentadol should be prescribed with care in patients with a history of seizure disorders or epilepsy.
- Tapentadol may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants such as serotonin reuptake inhibitors (SSRIs), serotonin-noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants, and antipsychotics.
- Serotonin syndrome has been reported when tapentadol is used in combination with serotoninergic antidepressants.
- Withdrawal of the serotoninergic medicine, together with supportive symptomatic care, usually brings about a rapid improvement in serotonin syndrome.

UKMI have produced a useful reference about Serotonin Syndrome - 'What is Serotonin syndrome and which Medicines cause it?' https://www.sps.nhs.uk/articles/what-is-serotonin-syndrome-and-which-medicines-cause-it-2/

Currently a medium severity warning appears on EMIS when tapentadol is co-prescribed with an antidepressant regarding increased risk of serotonin syndrome. EMIS also cautions use of tapentadol if a patient has epilepsy coded as a problem.

Prescribers should be aware that tapentadol immediate release (IR) is RAG rated **Black** (not recommended for use) and tapentadol modified release (MR) is RAG rated **Amber Initiated** (Specialist initiation of prescribing) on Pan Mersey formulary.

https://www.gov.uk/drug-safety-update/tapentadol-palexia-risk-of-seizures-and-reports-of-serotonin-syndrome-when-co-administered-with-other-medicines

SULFASALAZINE/SULFADIAZINE PRESCRIBING ERROR

We have been made aware of a prescribing incident in a neighbouring area whereby a patient was prescribed sulfadiazine instead of sulfasalazine:

A rheumatology patient was started on sulfasalazine 500mg tablets in hospital. Unfortunately this was incorrectly transcribed as sulfadiazine 500mg tablets by the GP practice. Sulfadiazine was prescribed and dispensed from June until the patient was admitted to hospital in December.

We would like to remind all healthcare professionals about the risk of look a-like/ sound a-like errors, particularly at the transfer of care across the interface and to remain vigilant when dealing with medicine names, which either look alike when written or sound alike.

Optimise Rx currently highlights the potential risk of this error occurring when sulfadiazine is picked, as follows:

"Sulfadiazine: not to be confused with sulfasalazine"

Please review the use of sulfadiazine and verify that this is not being mistaken for sulfasalazine, which has very different indications.

Details:

The MHRA drug safety update (2013) reports very serious incidents resulting from confusion between sulfadiazine and sulfasalazine. Sulfadiazine is indicated for the prevention of rheumatic fever. Sulfasalazine is indicated for the treatment of mild to moderate and severe ulcerative colitis and maintenance of remission; active Crohn's disease; and rheumatoid arthritis.

Community Pharmacists should contact the prescriber before dispensing if they have any doubt about which of these medicines is intended.

Please also refer to previous MHRA advice: https://www.gov.uk/drug-safety-update/recent-drug-name-confusion

EMOLLIENTS: NEW INFORMATION ABOUT RISK OF SEVERE AND FATAL BURNS WITH PARAFFIN-CONTAINING AND PARAFFIN-FREE EMOLLIENTS

Warnings about the risk of severe and fatal burns are being extended to all paraffin-based emollients regardless of paraffin concentration. Data suggest there is also a risk for paraffin-free emollients.

Advice for healthcare professionals:

- Ensure patients and their carers understand the fire risk associated with the build-up of residue on clothing and bedding and can take action to minimise the risk.
- When prescribing, recommending, dispensing, selling, or applying emollient products to patients, instruct them not to smoke or go near naked flames because clothing or fabric such as bedding or bandages that have been in contact with an emollient or emollient-treated skin can rapidly ignite.
- There is a fire risk with all paraffin-containing emollients, regardless of paraffin concentration, and it also cannot be excluded with paraffin-free emollients. A similar risk may apply for other products which are applied to the skin over large body areas or in large volumes for repeated use for more than a few days.
- Be aware that washing clothing or fabric at a high temperature may reduce emollient build-up but not totally remove it.
- Warnings, including an alert symbol, are being added to packaging to provide a visual reminder to patients and those caring for them about the fire hazard.

https://www.gov.uk/drug-safety-update/emollients-new-information-about-risk-of-severe-and-fatal-burns-with-paraffin-containing-and-paraffin-free-emollients

CLEXANE SHORTAGE

Sanofi have advised NHS England and Department of Health and Social Care (DHSC) that there has been a quality issue with a batch of Clexane 40mg that was due to arrive in January 2019.

Enoxaparin is available as the originator brand (Clexane®) and biosimilar brands (Inhixa® and Arovi®).

Prescribing should be by brand to ensure that the correct product is selected for prescribing, dispensing and administration and the patient receives the brand that they have been trained to use due to differences in syringe design.

If the brand is detailed in the discharge request, please ensure that the enoxaparin is prescribed by brand and please query any requests for generic enoxaparin with the requesting clinician.

The medicines management team is currently in the process of contacting patients to ensure any current generic prescribing is amended to the patient's usual brand. Community pharmacists should query any generically written prescriptions with the prescriber.

FREESTYLE LIBRE FLASH GLUCOSE SENSOR – USE OF BARRIER METHODS TO REDUCE SKIN REACTIONS TO THE SENSOR ADHESIVE

A Medical Device Alert has highlighted that some patients experiencing an immune response to the adhesive on the Freestyle Libre flash glucose sensor may be applying creams, patches or sprays under their sensor to reduce skin reactions, which may affect device performance.

Manufacturer's current guidance is:

Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the FreeStyle Libre system. Contact your health care professional before continuing to use the FreeStyle Libre system.

The alert recommends the following actions for all healthcare professionals who are responsible for or who use these devices:

- Identify patients who have reported or may be experiencing skin reactions, which may include erythema, itching and blistering.
- Consider if continued use of this device for patients with skin reactions is suitable.
- Consider use of alternative glucose monitoring systems for these patients.

The deadline for completion of these actions is 26th February 2019.

https://www.gov.uk/drug-device-alerts/freestyle-libre-flash-glucose-sensor-use-of-barrier-methods-to-reduce-skin-reactions-to-the-sensor-adhesive-mda-2019-003

VALPROATE MEDICINES: ARE YOU IN ACTING IN COMPLIANCE WITH THE PREGNANCY PREVENTION MEASURES?

MHRA have highlighted that although use of valproate medicines in female patients continues to slowly decline, there is wide variation in prescribing between Clinical Commissioning Groups (CCGs). NHS Halton CCG has been identified as a high prescriber of valproate in this group.

Advice and information for healthcare professionals:

- Valproate should not be used in women and girls of childbearing potential unless there is no suitable alternative and the conditions of the Pregnancy Prevention Programme are met.
- Although use in female patients in the UK continues to slowly decline, data shows a wide geographical variation in the prescribing of valproate medicines.
- Women continue to report instances when pharmacists have not provided a patient information leaflet or a 'patient card' when dispensing valproate.
- Ensure you are complying with the responsibilities of healthcare professionals involved in the care of female patients on valproate – including when valproate is used outside the licensed indications. (See advice for off-label use below)
- An audit function is available on all GP software systems – use this now to identify and recall all women and girls on valproate who may be of childbearing potential and refer to an appropriate specialist for a review.

Reminder for pharmacists:

- Always provide the statutory patient information leaflet to female patients with a valproate medicine, even when dispensed in a pharmacy 'white dispensing box' (plain carton).

- Remind women of the risks and provide with a 'patient card' every time they are dispensed a valproate medicine – situations can change and a one-time conversation is not sufficient.
- Check whether women are enrolled in the Pregnancy Prevention Programme and have signed a risk acknowledgement form – if not, dispense the prescription and advise the patient to speak to her GP as soon as possible (including by contacting the GP directly if necessary) for a specialist referral.
- GPhC inspectors will be systematically checking compliance with the Pregnancy Prevention Programme during inspections of registered pharmacies (see GPhC statement).
- Ensure materials are placed in a defined area in the pharmacy and that all staff, including locums, know where they are located and aware of the local policies.
- If you require more copies, contact the Sanofi medical information department without delay.

The medicines management team will be collecting data regarding current valproate prescribing within Halton during February 2019. NHS England is asking CCGs for organisational assurance of adherence to safety recommendations.
Please follow the link for more information:
https://www.gov.uk/drug-safety-update/valproate-medicines-are-you-in-acting-in-compliance-with-the-pregnancy-prevention-measures

HYDROCORTISONE MUCO-ADHESIVE BUCCAL TABLETS: SHOULD NOT BE USED OFF-LABEL FOR ADRENAL INSUFFICIENCY IN CHILDREN DUE TO SERIOUS RISKS

https://www.gov.uk/drug-safety-update/hydrocortisone-muco-adhesive-buccal-tablets-should-not-be-used-off-label-for-adrenal-insufficiency-in-children-due-to-serious-risks

Antimicrobial Stewardship and Resistance

Cheshire and Merseyside AMR Bulletins

The Antimicrobial Resistance (AMR) Board for Cheshire and Merseyside (C&M) was established in 2018. The Board is comprised of key participants from C&M who can influence antibiotic prescribing with the aim of reducing antibiotic resistance through tackling inappropriate prescribing.

The Board produces a monthly bulletin which contains some useful information regarding antimicrobial stewardship and resistance. All the bulletins are accessible via the Members section of the CCG website:
http://www.haltonccg.nhs.uk/members-practices/Pages/Cheshire---Merseyside-AMR-Bulletins.aspx

Education Resources for Treatment of UTIs

Health Education England has commissioned an educational film, in collaboration with Public Health England's Primary Care Unit on the treatment of UTIs in older adults for all out of hospital health and social care workers, introducing resources that can be used to diagnose, manage and prevent UTIs in out of hospital settings.

It supports staff to effectively treat older adults with UTI's, supporting existing Public Health England tools:

- TARGET UTI leaflet
- UTI diagnostics tool

They complement the other short films that have been supported in collaboration with PHE Primary Care Unit and TARGET Toolkit. It also promotes 'To Dip or Not to Dip' that aims to improve the management of urinary tract infections in older people in nursing home care. There is a link to educational resources for health and care workers. There is also a link to practical resources for health and care workers to share with patients and carers.

The film and resources are available on the e-LfH AMR site
There is also a recently launched HEE film available on antimicrobial stewardship for GPs

Medicines Supply Issues Update

Below is a link to the January/February issue of the 'Supply issues update for primary care'. This report has been produced by the Department of Health and Social Care (DHSC) Medicine Supply team and provides an update on current primary care medicine supplies issues.
http://www.haltonccg.nhs.uk/members-practices/medicines-management/medicines-supply-issues

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