

Our Ref: CL/NB

22nd November 2017

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To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Area Prescribing Committee Meeting on 11th October 2017 and 8th November 2017

The main outcomes of the meetings were: -

Shared Care / Amber-G Guidelines

DMARD shared care guideline (updated)

The DMARD shared care guideline has undergone a routine update. The DMARD monitoring requirements have been updated in line with the British Society of Rheumatology guidelines. Mycophenolate and Nordimet® (methotrexate injection) have also been included in the guideline.

Ivabradine amber-G guideline (updated)

The ivabradine Amber G guideline has been updated following changes to the SPC. The following changes have been made:

- The license for chronic stable angina has changed from patients with heart rate >60bpm to >70bpm
- Doses should only be titrated upwards if resting heart rate is persistently above 60bpm for all indications
- Heart failure patients with a resting heart rate between 50-60bpm should remain on maximum dose 5mg BD
- Combination with verapamil or diltiazem are now contraindications
- The following statement has been added regarding resting heart rate assessment and monitoring: Given that the heart rate may fluctuate considerably over time, serial heart rate measurements, ECG or ambulatory 24-hour monitoring should be considered when determining resting heart rate before initiation of ivabradine treatment and in patients on treatment with ivabradine when titration is considered. This also applies to patients with a low heart rate, in particular when heart rate decreases below 50 bpm, or after dose reduction.

Epilepsy shared care guideline (updated)

The shared care guideline covering the prescribing of anti-epileptics has been updated following a South Yorkshire collaborative approach with local CCGs. The following changes to the current Barnsley guideline have been agreed:

- Change of the traffic light status of brivaracetam from red to amber. Brivaracetam is a useful alternative in patients who are responding to levetiracetam but are experiencing intolerable side effects with levetiracetam.
- Inclusion of the drug eslicarbazepine (Zebinix®) as an alternative option for patients not responding to monotherapy or adjunctive therapy.

Shared care guidelines are available on the BEST website at the following link: <http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/>.

Prescribers (including secondary care clinicians) are encouraged to report any problems they experience with shared care or other medicines related issues, particularly where guidelines are not being complied with, to the following email address: BarnsleyAPCReport@nhs.net.

Prescribing Guidelines / Information

Prescribing of oral nutritional supplements (ONS) following discharge from secondary care

It has been agreed that requests for ONS on a D1 alone are deemed inappropriate requests and continued prescribing in primary care should only occur if there is a letter from a hospital dietitian stating that ONS should be continued and the reason(s) for this.

Generic desogestrel

The Committee has agreed that desogestrel should be prescribed generically instead of by brand name (e.g. Cerelle®, Cerazette®). There is no clinical reason why desogestrel should be prescribed as a brand and it is significantly more cost effective to prescribe generically.

Guidance for GPs on common off-label use of psychotropic medication (updated)

This guideline has undergone a routine update and has been enclosed with this memo.

Drugs prolonging the QTC interval and palliative care (new)

Guidance around the prescribing of drugs used in palliative care which prolong the QT interval has been produced by Dr Hirst at Barnsley Hospice. Palliative care patients in general may be at a higher risk of a prolonged QTc interval given the high prevalence of polypharmacy and metabolic disturbance. The guidance, which has been enclosed with this memo, includes implications for practice and prescribing hints.

Summary of formulary choices for BGTS (updated)

The current formulary choices for blood glucose testing strips have been updated to include the Glucomen Areo® and Glucomen Areo Ketone® test strips. A copy of the guideline has been enclosed with this memo.

COPD algorithm (updated)

The COPD guideline has been updated into a simpler format than the current guideline. It has been approved by the Committee and is in the process of being shared with the LMC.

FreeStyle Libre® flash glucose monitoring device (new)

FreeStyle Libre® is a flash glucose monitoring (Flash GM) system which monitors glucose levels using interstitial fluid levels. The FreeStyle Libre® device became available on NHS prescription on the 1st November 2017.

The following *interim* recommendations were made at the APC meeting in October:

- The use of FreeStyle Libre® for all patients with type 1 and type 2 diabetes is not recommended.
- FreeStyle Libre® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by the National Institute for Health and Care Excellence (NICE), is not recommended for routine funding in primary care.

However, following further consultation with the Diabetes Specialist Team, the use of FreeStyle Libre® was reconsidered at the APC meeting in November with a view to allowing prescribing for patients who sit within clearly defined patient groups. Guidance is currently being produced which will define these patient groups and the guidance will also specify the outcomes that must be monitored to ensure use of the device is leading to an improvement in these outcomes. The guidance will be discussed at the APC meeting in December.

The Barnsley Joint Formulary can be accessed at the following link:
<http://www.barnsleyformulary.nhs.uk/>

Prescribing guidelines are available on the BEST website at the following link:
<http://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/>

Traffic Light Classifications

The Committee assigned the following classifications to the products included in the tables below.

Changes from the October meeting:

| Drug | Indication | Traffic light status |
|--|--|---|
| Desogestrel (generic) | Oral contraception | Green |
| Tadalafil 2.5mg and 5mg (Cialis®) | Erectile dysfunction | Provisional grey |
| Horizon scanning document | | |
| Enoxaparin sodium (biosimilar) 2,000, 4,000, 6,000, 8,000 & 10,000 IU solution for injection inn pre-filled syringe (Inhixa®▼, Techdow Pharma) | Treatment and prophylaxis of thromboembolism | Provisional amber. There are now two enoxaparin products available, Clexane® (enoxaparin) and Inhixa® (enoxaparin biosimilar). It is therefore recommended that enoxaparin is prescribed by brand. Both enoxaparin preparations are non formulary. |

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|--|--|---|
| Levonorgestrel 19.5 mg intrauterine delivery system (Kyleena [®] , Bayer) | Indicated for contraception for up to 5 years. | Provisional green |
| Idarubicin (generic) 5 mg/5 mL, 10 mg/10 mL & 20 mg/20 mL solution for injection (Accord) | Indicated for AML and ALL | Provisional red |
| Fluoxetine (generic) 10 mg film-coated tablets (Par Laboratories) | Depression, Obsessive compulsive disorder, bulimia nervosa | Provisional grey due to high cost Please note: <i>Fluoxetine capsules and dispersible tablets are green on the traffic light list.</i> |
| Patiromer sorbitex calcium 8.4 g, 16.8 g, 25.2 g powder for oral suspension (Veltassa [®] ▼, Vifor Fresenius) | Indicated for the treatment of hyperkalaemia in adults. | Provisional red |

Changes from the November meeting:

| Drug | Indication | Traffic light status |
|--|---|----------------------|
| New Product Application | | |
| Eslicarbazepine (Zebinix [®]) | Epilepsy | Amber |
| Horizon scanning document | | |
| Ex vivo expanded autologous human corneal epithelial cells containing stem cells 79,000-316,000 cells/cm ² living tissue equivalent (Holoclar [®] ▼i) NICE: TA467 | Indicated for treatment of adult patients with moderate to severe limbal stem cell deficiency | Provisional red |
| Cladribine 10 mg tablets (Mavenclad [®] , Merck) NICE: TA due Feb 2018 | Treatment of adult patients with highly active relapsing multiple sclerosis (MS) | Provisional red |
| Methotrexate 100 mg/mL concentrate for solution for infusion (medac GmbH) | Treatment of various types of cancer | Provisional red |
| Mercaptamine 3.8 mg/mL eye drops (Cystadrops [®] ▼, Orphan Europe) | Indicated for the treatment of corneal cystine crystal deposits | Provisional red |
| Avelumab 20 mg/mL concentrate for solution for infusion (Bavencio [®] ▼, Pfizer) | Monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (MCC). | Provisional red |
| Telotristat ethyl 250 mg film-coated tablets (Xermelo [®] ▼, Ipsen Ltd) | Treatment of carcinoid syndrome diarrhoea | Provisional red |
| Atezolizumab 1,200 mg concentrate for solution for infusion (Tecentriq [®] ▼, Roche) | Metastatic urothelial carcinoma (UC). Non-small cell lung cancer | Provisional red |

| | | |
|---|---|-------------------------|
| Bosentan 62.5 mg & 125 mg film-coated tablets (Bosentan Accord, Accord) | Pulmonary arterial hypertension (PAH) Indicated to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease | Already on the red list |
| Migalastat HST4 (https://www.nice.org.uk/guidance/hst4) | Fabry's disease | Red |

MHRA Drug Safety Update

The September MHRA Drug Safety Update can be accessed at the following link:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/647375/DSU-Sept-pdf.pdf

Issues relating to primary care:

Miconazole (Daktarin®): over-the-counter oral gel contraindicated in patients taking warfarin

Patients taking warfarin should not use over-the-counter miconazole oral gel (Daktarin®). If you plan to prescribe miconazole oral gel in a patient on warfarin, you should closely monitor them and advise that if they experience any sign of bleeding, they should stop miconazole oral gel and seek immediate medical attention.

Advice for healthcare professionals:

- Bleeding events, some with fatal outcome, have been reported with use of miconazole oral gel by patients on warfarin
- Patients taking warfarin should not use over-the-counter miconazole oral gel available from pharmacies
- If the concomitant use of miconazole oral gel with an oral anticoagulant such as warfarin is planned, exercise caution and ensure that you monitor and titrate the anticoagulant effect carefully
- Advise patients taking prescription-only miconazole oral gel and warfarin that if they experience signs of over-anticoagulation, such as sudden unexplained bruising, nosebleeds, or blood in urine, they should stop using miconazole and seek immediate medical attention

The October MHRA Drug Safety Update can be accessed at the following link:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/655127/DSU-Oct-pdf.pdf

Issues relating to primary care:

Methylprednisolone injectable medicine containing lactose (Solu-Medrone® 40 mg): do not use in patients with cows' milk allergy

Gabapentin (Neurontin®): risk of severe respiratory depression

Gabapentin has been associated with a rare risk of severe respiratory depression even without concomitant opioid medicines. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of central nervous system (CNS) depressants, and elderly people might be at higher risk of experiencing severe respiratory depression. Dose adjustments might be necessary in these patients

Advice for healthcare professionals:

- Be aware of the risk of CNS depression, including severe respiratory depression, with

gabapentin

- Consider whether dose adjustments might be necessary in patients at higher risk of respiratory depression, including elderly people, patients with compromised respiratory function, respiratory or neurological disease, or renal impairment, and patients taking other CNS depressants
- Report any suspected adverse reactions on a [Yellow Card](#)

Isotretinoin (Roaccutane®): Rare reports of erectile dysfunction and decreased libido

Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

If constipation occurs during treatment with clozapine (Clozaril®, Denzapine®, Zaponex®), it is vital that it is recognised and actively treated.

Advice to healthcare professionals:

- The antipsychotic drug clozapine has been associated with varying degrees of impairment of intestinal peristalsis; this effect can range from constipation, which is very common, to very rare intestinal obstruction, faecal impaction, and paralytic ileus
- Exercise particular care in patients receiving other drugs known to cause constipation (especially those with anticholinergic properties), patients with a history of colonic disease or lower abdominal surgery, and in patients aged 60 years and older
- Clozapine is contraindicated in patients with paralytic ileus
- Advise patients to report constipation immediately
- Actively treat any constipation that occurs

Regards



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cc: Medicines Management Team
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Area Prescribing Committee Members (Secretary to the APC to circulate)
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ENC: Guidance for GPs on common off-label use of psychotropic medication
Drugs prolonging the QTc interval and palliative care
Guidelines for the choice of blood glucose testing strips and meters