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Clinical Commissioning Group

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Our Ref: DC/NB

10th December 2020

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Area Prescribing Committee Meeting on 11th November 2020

The main outcomes of the meeting were: -

Prescribing Guidelines

The following prescribing guideline was approved by the Committee:

Treatment of overactive bladder in women guidance [UPDATED]
This guidance has been updated in line with NICE NG123: Urinary incontinence and pelvic organ prolapse in women: management

Changes to the OAB treatment algorithm include:

- Solifenacin is now a first line treatment option when a once daily preparation is required (previously second line).
- Tolterodine immediate release and tolterodine MR once daily (Neditol®XL) are now second line treatment options (previously first line).
- Oxybutynin MR 5mg and 10mg tablets (Lyrinel® XL) have been removed from the algorithm and are now non-formulary
- Darifenacin MR 7.5mg and 15mg tablets have been removed from the algorithm.
- Solifenacin oral solution 1mg/ml SF has been added to the formulary with a green classification as a second line option if the patient has swallowing difficulties or is unable to tolerate a solid formulation (oxybutynin patch 3.9mg/24 hours (Kentera®) remains first line if a solid dose formulation is unsuitable).
- Information has been added on offering a treatment break where clinically appropriate if patients have been on an antimuscarinic drug for at least 6 months.

The updated guidance is available on the BEST website:
https://best.barnsleyccg.nhs.uk/Over%20active%20bladder%20-%20treatment%20algorithm.pdf.

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

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

Shared Care / Amber-G Guidelines

The following shared care guidelines were approved by the Committee and are available on the BEST website at the links below:

Insulin Aspart (Fiasp®) Amber-G guideline [UPDATED]
Information has been added on the use of Fiasp® in the paediatric population.

The following guidelines have received minor amendments:

- Ivabradine (Procoralan®) Amber-G guideline [UPDATED]
- Rifaximin (Targaxan®▼) Amber-G guideline [UPDATED]
- Shared Care Guideline for Entresto® in the management of Chronic Heart Failure [UPDATED]
- Sodium Clodronate (Bonefos®) shared care guideline for the treatment and prevention of bone disease in multiple myeloma [UPDATED]

Shared Care and Amber-G guidelines are available on the BEST website:
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.

The Barnsley Interface Issues Form should be used to report such problems:
http://www.barnsleyccg.nhs.uk/members-professionals/area-prescribing-committee.htm

Other

Melatonin formulary preparations

The Committee reviewed the melatonin section of the formulary and the key changes are summarised in the following table*. The melatonin shared care guideline is in the process of being updated and will include further information.

Nifedipine formulary preparations

The Committee reviewed the nifedipine section of the formulary following stock availability issues with a number of different nifedipine preparations.

It was agreed that the following preparations would be included on the formulary and the formulary changes are summarised in the table below**:
One daily preparations: Adipine® XL and Coracten® XL (currently on the formulary).
Twice daily preparations: Coracten® SR and Tensipine® MR

Nifedipine preparations should be prescribed by brand as different versions of nifedipine MR preparations may not have the same clinical effect.

Traffic Light Classifications

The Committee assigned the following classifications to the products included in the table below:

Drug	Formulary Indication	Traffic light status (Drugs with a provisional classification are not currently included on the Barnsley formulary)
Horizon Scanning Document – October 2020		
Bempedoic acid 180 mg film-coated tablets (Nilemdo▼®, Daiichi Sankyo UK Limited)	Indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet.	Non-formulary provisional grey
Bempedoic acid / ezetimibe 180 mg/10 mg film-coated tablets (Nustendi▼®, Daiichi Sankyo UK Limited)	Indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet.	Non-formulary provisional grey
Melatonin 3 mg film coated tablets (Syncrodin®, Pharma Nord UK)	Indicated for the short-term treatment of jet lag in adults	Non-formulary provisional grey
Atorvastatin (generic) 30 mg, 60 mg film coated tablets (Zentiva)	• Hypercholesterolaemia • Prevention of cardiovascular disease in adult patients estimated to have a high risk for a first cardiovascular event as an adjunct to correction of other risk factors	Non-formulary provisional grey (Atorvastatin 10mg, 20mg, 40mg and 80mg remain formulary green)
Treatment of overactive bladder in women guidance		
Oxybutynin MR (Lyrinel® XL)	Urinary frequency/ urinary urgency/incontinence	Non formulary provisional green (previously formulary green)
Solifenacin 1mg/ml oral solution SF.	Urinary frequency/ urinary urgency/incontinence	Formulary green Second line option if swallowing difficulties or unable to tolerate solid formulation (oxybutynin patch 3.9mg/24 hours (Kentera®) is first line if solid dose formulations are unsuitable)
***Melatonin Formulary Changes** (the melatonin shared care guideline is currently being updated)		
Melatonin (Circadin® 2mg PR tablets).	Circadin® is the **first line choice** melatonin preparation for children/ adolescents **without** ASD and/or Smith-Magenis syndrome **(off label use)** for both MR and immediate release.	Formulary amber For an immediate release dose Halve, quarter or crush Circadin® PR tablets **(off label use).** SWYFT have produced a patient information leaflet which provides advice on crushing: https://www.swyapc.org/wp-content/uploads/2017/01/Advice-on-crushing-Circadin-tablets.pdf Swallowing difficulties For an immediate release dose – see above. If a prolonged release dose is indicated in a patient with swallowing difficulties consider Slenyto® prolonged release tablets (smaller in size than Circadin®). Refer to Slenyto® entry below for administration information.
Melatonin 1mg and 5mg prolonged-release tablets (Slenyto®)	**Restricted** to children /adolescents with ASD and/or Smith Magenis syndrome. Also off label use if swallowing difficulties (e.g. can't swallow Circadin® - Slenyto® is smaller in size) and MR preparation needed.	Formulary amber (previously non-formulary provisional amber) For an immediate release dose Halve, quarter or crush Slenyto® PR tablets **(off label use).**

		Swallowing difficulties For an **immediate release** dose – see above. For a **prolonged release** dose, tablets can be put into soft food such as yoghurt, orange juice or ice cream to facilitate swallowing. The tablet should not be broken, crushed or chewed because it will lose the PR properties.
Melatonin 1mg/ml oral solution (Colonis®)	**Restricted** to children/ adolescents who require medication to be administered via a feeding tube (off label use)	Formulary amber restricted (previously non-formulary provisional grey) **Contains propylene glycol 150.5 mg/ml and sorbitol 140mg/ml which may be potentially problematic in children.** **The total daily dose of excipients needs be calculated and checked by initiating prescriber to ensure they are within the safety limits for the age and weight of the patient. Particular care should be exercised in young children (4 years and under).** Propylene glycol maximum daily safety limit 1 month – 4 years: 50mg/kg 5 years – 17 years: 500mg/kg *E.g. melatonin doses greater than 5.3mg in a 2 year old weighing 16kg or 7.65mg in a 4 year old weighing 23kg would exceed safety limits.* Sorbitol maximum daily safety limit All ages of children: Greater than 140mg/kg/day may result in GI symptoms. Sorbitol may also affect the bioavailability of other medicinal products administered concomitantly.
Nifedipine formulary changes		
Adipine XL®	Hypertension/angina prophylaxis	Formulary green Once daily preparation
Coracten SR®	Hypertension/angina prophylaxis	Formulary green Twice daily preparation
Tensipine MR®	Hypertension/angina prophylaxis	Formulary green Twice daily preparation
Gastro-intestinal system chapter formulary review		
Ranitidine	H_2 - receptor antagonist	Formulary grey (previously formulary green but all formulations of ranitidine are out of stock long term) Patients currently prescribed oral ranitidine should be identified and reviewed on an individual basis to establish if ongoing treatment is still required. If ongoing treatment is still

		required, then consider switching to an alternative oral treatment. Local guidance has been developed and will be on the BEST website in due course.
Sucralfate	Gastric/duodenal ulceration, chronic gastritis	Formulary red (previously formulary green) Unlicensed special order product (high cost)
Pancreatin (Creon® 25000)	Pancreatic insufficiency	Formulary amber-G (Creon® 10000 is already amber-G) BNF advice: It is important to ensure adequate hydration at all times in patients receiving higher-strength pancreatin preparations
Skin chapter formulary review		
Barrier preparations: Zinc and caster oil cream, Drapolene® cream, Metanium® ointment, Morhulin® ointment, Sudocrem® cream	Nappy rash	Formulary grey (previously formulary green) Nappy rash is included in the Barnsley self-care guidance: https://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/Self_Care_Guidance.pdf?UNLID=516187989202011181457 22
Hydroxychloroquine	Discoid lupus erythematosus	Formulary red for dermatological indication (formulary amber for rheumatology)
Benzoyl peroxide	Acne	Formulary grey (previously formulary green) Mild acne is included in the Barnsley self-care guidance: https://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/Self_Care_Guidance.pdf?UNLID=516187989202011181457 22
Salicylic acid wart and verrucae products (Salactol®, Salactac®, Verrugon®)	Treatment of warts and verrucae	Formulary grey (previously non-formulary) Treatment of warts and verrucae is included in the Barnsley self-care guidance: https://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/Self_Care_Guidance.pdf?UNLID=516187989202011181457 22
Other		
Cleen® Ready to use Enema 133ml	Osmotic laxative (phosphate enema)	Formulary green (Cleen® ready to use enema has replaced Fleet® ready to use enema) **Cleen®** ready to use enema 133ml is now the **first line choice** phosphate enema Phosphates Enema (Formula B) 128ml is **second line choice** phosphate enema
Gamolenic acid (evening primrose oil)	Unlicensed	Non formulary grey The licenses for Efamast (previously used for mastalgia) and Epogam (previously used for atopic eczema)

		were withdrawn by the MHRA in 2002 due to a lack of evidence of efficacy following a review by the CSM. Gamolenic acid is not recognised as a food supplement within the Drug Tariff and it does not appear as a medicine in the BNF. No further evidence has been found to support its use in pre-menstrual syndrome, rheumatoid arthritis or multiple sclerosis. Due to lack of evidence of efficacy, it should not be prescribed at NHS expense.

MHRA Drug Safety Update

The October 2020 MHRA Drug Safety Update can be accessed at the following link:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/928774/Oct-2020-DSU-PDF.pdf

Issues relating to primary care:

Warfarin and other anticoagulants: monitoring of patients during the COVID-19 pandemic

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

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.

Report on a Yellow Card

Suspected adverse drug reactions should be reported to the Yellow Card Scheme. Any suspected adverse drug reactions associated with any medicine used in patients with confirmed or suspected COVID-19, including medicines to manage long-term or pre-existing conditions such as anticoagulant medicines, should be reported to the COVID-19 Yellow Card reporting site.

Regards

Deborah Cooke
Lead Pharmacist

cc: Medicines Management Team
Rebecca Hoskins, BHNFT
Sarah Petty, BHNFT
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Sarah Hudson, SWYPFT
Area Prescribing Committee Members (Secretary to the APC to circulate)
Local Medical Committee (Secretary to the LMC to circulate)
Gary Barnfield, NHS Sheffield CCG
Alex Molyneux, NHS Doncaster CCG
Stuart Lakin, NHS Rotherham CCG