NHS
South Yorkshire
Integrated Care Board

South Yorkshire Integrated Care Board
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Our Ref: DC/NB

10th October 2022

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Area Prescribing Committee Meetings on 10th August and 14th September 2022

The main outcomes of the meetings were: -

Prescribing Guidelines

The Committee endorsed the following Barnsley prescribing guidelines:

Barnsley Mucolytic Prescribing Guidance [NEW]
This guidance has been developed to support the Primary Care Medicines Optimisation Scheme. Practices are required to review patients prescribed carbocisteine in line with local and national guidance.

Key points:

- Carbocisteine 375mg capsules and acetylcysteine 600mg effervescent tablets (NACSYS®) both have a green classification on the Barnsley Formulary. Acetylcysteine should be prescribed as the brand NACSYS® as some acetylcysteine preparations have a high cost.

- The initial dose of **carbocisteine** is 2.25g daily in divided doses (2 x 375mg capsules TDS). Carbocisteine should be reviewed 4-8 weeks after initiation to consider dose reduction to the maintenance dose of 1.5g daily in divided doses (2 x 375mg BD or 375mg QDS) if the patient is benefitting from treatment, or to stop the carbocisteine if no benefit is apparent.

- The dose of **NACSYS®** is ONE sugar-free effervescent tablet of 600 mg, dissolved in half a glass of water, once daily. The dose does not require review, however all oral mucolytic therapy for COPD requires reviewing after 4-8 weeks in order to assess if there has been symptomatic improvement. Therapy should only be continued if there is symptomatic relief.

- **If a mucolytic in liquid form is required, NACSYS® (acetylcysteine effervescent tablets) is the most cost-effective option**. If a liquid form of carbocisteine is required, carbocisteine 750mg/10ml sugar-free sachets are the most cost-effective option.

The guidance is available on the BEST website at the following link:
Mucolytic Pathway Aug 2022.pdf (barnsleyccg.nhs.uk).

Management of Stable COPD [MINOR UPDATES]
This guidance has received minor updates and is available on the BEST website at the following link:
https://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/COPD%20inhaled%20therapies.pdf

Oral Nutritional Supplements (ONS) Prescribing Guidelines in Primary Care: Adults aged 18 years and over [UPDATED]
This guidance has been updated and the main changes are as follows:

- 'Dysphagia' has been removed as a 'standard' ACBS prescribing criteria for ONS.
- A new 'Compact' ONS prescribing algorithm has been added. Aymes® Actagain 600 has recently been added to the formulary with an Amber-G classification. One 250ml bottle of Aymes® Actagain 600 is the nutritional equivalent of two 125ml Ensure® Compact with over a 40% lower daily acquisition cost. If a liquid compact product is required, Aymes® Actagain 600 OD is preferred to Ensure® Compact BD. Aymes® Shake Compact (powder for reconstitution with milk) remains one of the first line options in the 'Compact' range as it is more cost-effective.
- The food first leaflet within appendix 1 has been updated.

The updated guideline is available on the BEST website at the following link:
https://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/Oral_Nutritional_Supplements_Algorithm.pdf

Prescribing of Sodium-Glucose Cotransporter-2 Inhibitors (SGLT2 inhibitors) and risk of Diabetic Ketoacidosis (including in patients with COVID-19) [UPDATED].
This guidance was produced at the start of the pandemic at the request of diabetes specialists. Changes include:

- The removal of the type 1 diabetes indication for dapagliflozin, since the authorisation holder for dapagliflozin withdrew the indication for type 1 diabetes mellitus. This is not due to any new safety concerns and the other indications for dapagliflozin are unchanged.
- In line with the updated Guidelines for approved choice of Blood Glucose Testing Strips, Meters and Lancets, patients prescribed SGLT2 inhibitors would not usually be issued with a ketone testing meter (unless identified as high risk of recurrent diabetic ketoacidosis by the diabetes specialist team). Their ketone levels should be checked if they present as unwell in line with sick day guidance, using a practice meter, even if their blood glucose is in the normal range.

The updated guideline will be available on the BEST website in due course.

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 Guidelines

The Committee endorsed the following shared care/amber-G guidelines:

DMARDs: Shared Care Guideline for the Prescribing of Disease Modifying Antirheumatic Drugs (DMARDs) in Rheumatology Patients [MINOR UPDATES]
Changes have been made to the hydroxychloroquine and the sulfasalazine sections.

The hydroxychloroquine section has been updated in line with the MHRA Drug Safety Update February 2022; https://www.gov.uk/drug-safety-update/hydroxychloroquine-chloroquine-increased-risk-of-

cardiovascular-events-when-used-with-macrolide-antibiotics-reminder-of-psychiatric-reactions and updated Royal College of Ophthalmologists guidance on monitoring of hydroxychloroquine; https://www.rcophth.ac.uk/news-views/hydroxychloroquine-and-chloroquine-retinopathy/

The changes to the sulfasalazine section include the addition of psychiatric reactions as an adverse drug reaction. Information has been added to note that the specialist team advise that patients on sulfasalazine should stop medication if they have an infection that requires treatment with antibiotics or antiviral medication, or if they feel too unwell to work or confined to bed or house.

The section relating to the disposal of sharps bins includes a link to the information on the BEST website which has previously been circulated in primary care https://best.barnsleyccg.nhs.uk/clinical-support/shared-care-guidelines/dmards-rheumatology-sharps-bin/16228

The updated shared care guideline will be available on the BEST website in due course.

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

Cenobamate (Ontozry®) information for Community Pharmacies [NEW]
Cenobamate has recently been assigned an amber classification on the Barnsley Formulary for use in line with the South Yorkshire and Bassetlaw Adult Epilepsy Shared Care Guideline. This information has been produced to support community pharmacies with the ordering of cenobamate to ensure continuity of supply for patients.

The guidance has been enclosed with this memo and will be updated when further information becomes available.

Choice of Direct Oral Anticoagulant (DOAC) for prevention of stroke and systemic embolism in adults with non-valvular AF (NVAF) Area Prescribing Committee Position Statement
The position statement which was approved in the June meeting is now available on the BEST website: https://best.barnsleyccg.nhs.uk/prescribing-guidelines/cvs-choice-of-doac-for-prevention-of-stroke-and-systemic-embolism-in-adults-with-nvaf-apc-position-statement-apc-approved/618139

Prescribers are reminded that where a DOAC is considered to be the most appropriate anticoagulant for patients with NVAF, edoxaban (Lixiana®) is to be used first line unless there is a specific clinical reason not to do so. Refer to the position statement for further information.

South Yorkshire Trans man and Trans women Prescribing Guidelines [UPDATED]
The updated guidelines are available on the Sheffield Health and Social Care NHS Trust website via the links below and links will also be added to the BEST website. The Barnsley Area Prescribing Committee has approved these guidelines for use by prescribers within primary care who choose to prescribe within their scope of practice.

- Trans man medication (This applies to a person assigned female, cis-female, at birth undertaking gender transition to become a male)

- Trans woman medication (This applies to a person assigned male, cis male, at birth undertaking gender transition to become a female)

The guidelines now include:

- Details of an organisation that can support patients waiting to see a specialist - Gendered Intelligence. This is a free trans-led, confidential help and support service for patients waiting for their first appointment with a Gender Identify Clinic (refer to appendix 3 within the guidelines for further information)
- Updated information on monitoring and how primary care can access support from the specialist service should this be required. The guidelines recommend monitoring 3 monthly for the first 12 months, then 6 monthly for 2 years and then annually thereafter.
- More details have been added around screening programmes, as changing gender / registered sex affects this.

Shortec® Liquid Discontinuation

Shortec® liquid (oxycodone 1mg/ml oral solution) and Shortec® concentrate (oxycodone 10mg/ml oral solution) have been discontinued by the manufacturer. The Committee agreed that oxycodone liquid should be prescribed generically. It was noted that particular care should be exercised when prescribing oxycodone liquid to ensure that the intended preparation is selected (standard solution or the concentrated solution) and information is included on Scriptswitch around this.

Oxycodone solid oral dose forms should continue to be prescribed as Shortec® (oxycodone standard release) and Longtec® (oxycodone prolonged release).

Metolazone

A new UK licensed metolazone preparation is available (Xaqua®) which has up to a two-fold difference in bioavailability compared to the unlicensed and imported metolazone preparations currently in use. Further work will be undertaken to look at this in more detail and the amber G guideline will be reviewed in due course. The Committee agreed that patients should be maintained on their existing product to reduce the risk of inadvertent switching and brand prescribing is therefore now advised. Refer to the traffic light classifications table below for further information.

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)**
SPS New Medicines Newsletter June 2022		
Dexamethasone and levofloxacin (*Ducressa*®) 1mg/5mg in 1mL eye drops	Prevention and treatment of inflammation, and prevention of infection associated with cataract surgery	Non-formulary provisional grey
Tixagevimab and cilgavimab (*Evusheld*®) 150mg in 1.5mL tixagevimab vial and 150mg in 1.5mL cilgavimab vial	Pre-exposure prophylaxis of COVID-19	Formulary red restricted
SPS New Medicines Newsletter July 2022		
Trifarotene (*Aklief*®) 50microgram/g cream in 75g pump	Acne vulgaris	Non-formulary provisional grey

SPS New Medicines Newsletter July 2022 – Changes to formulary wording only		
Beclometasone + formoterol + glycopyrronium (*Trimbow*®) **MDI** 172micrograms/5micrograms/ 9micrograms inhaler	Asthma	Trimbow® MDI is formulary green Addition of the following wording to Trimbow® MDI entry: Trimbow® MDI 87micrograms / 5micrograms / 9micrograms is included in the COPD guidelines Trimbow® MDI 172micrograms / 5micrograms / 9micrograms is licensed for the treatment of asthma only.
Metolazone (*Xaqua*®) 5mg tablet	Oedema and hypertension	Metolazone is formulary Amber-G Addition of the following wording to metolazone entry: UK-licensed metolazone tablets (Xaqua®) have up to two-fold difference in bioavailability compared to other (unlicensed, imported) metolazone preparations. **Patients should be maintained on their current brand of metolazone. Metolazone should be prescribed by brand.** For further information refer to the SPS: Example medicines to prescribe by brand name in primary care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice And BNF: MedicinesComplete — CONTENT > BNF > Drug: Metolazone The metolazone Amber-G guidance will be reviewed in due course.
Other		
Paliperidone prolonged release injection (Trevicta®)	Treatment and maintenance of schizophrenia	Formulary red (previously non-formulary provisional red)
Risperidone prolonged release injection (Okedi®)	Treatment of schizophrenia	Non-formulary provisional red
Darifenacin	Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in adult patients with overactive bladder syndrome.	Non-formulary provisional grey (previously formulary green)
Icosapent ethyl	In line with TA805 - Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides	Formulary red (previously non-formulary provisional grey) To be reclassified as Amber once Shared Care Guidance is developed
Fluticasone 50mcg/ Azelastine137mcg nasal spray (Dymista®)	Moderate to severe seasonal and perennial allergic rhinitis	Formulary green (previously non-formulary provisional grey) The combination product containing both azelastine and fluticasone should be reserved for those with persistent symptoms, in whom the combination of an oral antihistamine and an intra-nasal corticosteroid has been tried and found to be sufficiently ineffective. The oral antihistamine can then be stopped. It should not be used as a first-line therapy.

		Management of Allergic Rhinitis in Primary Care Guidelines will be updated in due course.
Ivermectin cream (Soolantra®)	Inflammatory lesions of rosacea (papulopustular)	Formulary green (previously non-formulary provisional red)
Other - Changes to formulary wording only		
Oxycodone (Shortec®)	Opioid analgesic	Addition of the following wording to oxycodone immediate release entry: **Shortec® liquid** has been discontinued. Oxycodone liquid should be prescribed generically. Note that there are two strengths of oxycodone liquid: 5mg/5ml oral solution and 10mg/1ml (high strength) oral solution.
Co-careldopa (Sinemet®)	Parkinson's disease	Co-careldopa is formulary amber. It is now more cost effective to prescribe generically, wording to prescribe as the brand Sinemet® has been removed.

MHRA Drug Safety Update

The July and August 2022 MHRA Drug Safety Updates can be accessed at the following links:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1092865/July-2022-DSU-PDF.pdf
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1099718/Aug-2022-DSU-PDF.pdf

Issues relating to primary care:

Topiramate (Topamax): start of safety review triggered by a study reporting an increased risk of neurodevelopmental disabilities in children with prenatal exposure
The MHRA have initiated a new safety review into topiramate as a result of an observational study reporting an increased risk of neurodevelopmental disabilities in children whose mothers took topiramate during pregnancy. Topiramate is known to be associated with an increased risk of congenital malformations and effects on fetal growth if used during pregnancy. Continue to counsel patients who can become pregnant on the known and emerging risks of topiramate for an unborn baby and on the need to use effective contraception throughout use.
Advice for healthcare professionals: • the MHRA have started a new safety review to assess the benefits and risks of topiramate and to consider whether further measures are required to reduce the risk of harm associated with topiramate use during pregnancy • the new safety review was triggered by a large observational study reporting that prenatal exposure to topiramate is associated with an increased risk of autism spectrum disorders, intellectual disability, and neurodevelopmental disorders • of the antiepileptic medicines reviewed for use in pregnancy, lamotrigine and levetiracetam continue to be considered the safer for the baby since they were not associated with an increased risk of birth defects – see advice following comprehensive safety review of antiepileptic drugs in pregnancy

- it remains vital that the strict restrictions for valproate prescribing in women and girls of childbearing potential are followed given the known significant risks if valproate is used in pregnancy (see dedicated section on page 5 of the full alert)

Reminder of current advice for topiramate:

- do not prescribe topiramate during pregnancy for migraine prophylaxis
- ensure any patients of childbearing potential know to use highly effective contraception throughout treatment with topiramate
- counsel patients on the importance of avoiding pregnancy during topiramate use due to these emerging data and also the established increased risks of major congenital malformations and fetal growth restriction in babies exposed to topiramate in-utero
- topiramate may reduce the effectiveness of steroidal contraceptives, including oral contraceptives, therefore consider alternative or concomitant methods (see section on Advice on contraceptive interactions on page 5 of the full alert)
- for migraine prophylaxis, topiramate can be withdrawn in pregnancy by an appropriate prescriber but alternative treatments should be considered
- for epilepsy, urgently refer anyone on topiramate who is planning a pregnancy or who is pregnant for specialist advice on their antiepileptic treatment

Advice to provide to patients:

- do not stop taking topiramate without first discussing it with your doctor
- topiramate can harm the way an unborn baby grows and develops during pregnancy – see advice on epilepsy medicines and pregnancy
- a new study has also linked topiramate to an increased risk of autism spectrum disorders and intellectual disabilities (effects on learning and development) in children exposed to it during pregnancy
- the MHRA and its independent experts are investigating whether there needs to be changes to how topiramate can be used in UK patients – we will communicate the outcomes of this review once it has concluded
- if you are taking topiramate for epilepsy and are planning a pregnancy, urgently talk to your doctor for a specialist review – there are other epilepsy medicines that are not associated with an increased risk of birth defects in pregnancy
- if you are taking topiramate for migraine and planning a pregnancy, talk to your prescriber about alternative treatments that can be used in pregnancy as soon as possible
- anyone who is able to get pregnant should have a pregnancy test before they start topiramate treatment and use effective contraception while taking topiramate
- topiramate can reduce the effectiveness of hormonal contraception in preventing unplanned pregnancy – talk to a healthcare professional about the best contraception for you while you are taking topiramate

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists

Use of a nebuliser purchased independently of medical advice for use in the home to deliver nebulised asthma rescue medications to children can mask a deterioration in the underlying disease and may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates. If home use of a nebuliser for the acute treatment of asthma in children under 18 years of age is considered necessary, this should be initiated and managed by an appropriate specialist. This is consistent with current clinical guidance.

Advice for healthcare professionals:

- use of nebuliser devices at home to deliver asthma rescue medication to children and adolescents, without adequate medical supervision, can mask a deterioration in the underlying

disease, which could result in delays in seeking medical attention and have fatal or serious consequences

- only specialists in asthma should initiate and clinically manage use of nebulisers and associated nebulised medicines at home for acute treatment of asthma in children and adolescents (see definition of specialists on page 3 of the full alert)
- independent purchase of nebuliser devices outside of medical advice for use at home to deliver rescue therapy for the acute treatment of asthma in children and adolescents is not recommended
- pharmacists are asked to advise people seeking to purchase a nebuliser for this purpose that such home use of nebulisers is not recommended without specialist clinical management
- continue to report suspected adverse reactions to nebulised medications and adverse incidents involving nebulisers on a Yellow Card

Advice to provide to patients or caregivers:

- seek urgent medical assistance **if worsening asthma symptoms are not relieved by rescue medicines** prescribed by a healthcare professional, even if the child has short-term recovery following use of prescribed nebulised medication
- children under 18 years should only use a nebuliser to take asthma reliever medications under specific instructions of a doctor with expertise in asthma, so that deterioration in asthma control can be detected and treated without delay
- only use a nebuliser device recommended by a doctor and ask for training from your asthma nurse, pharmacist, or other healthcare professional on how it should be used and maintained and when to seek medical advice
- if your child or teenager have been using a nebuliser at home, and have not yet been referred to a specialist in asthma, talk to their GP about referral to a specialist

Regards

Deborah Cooke
Lead Pharmacist

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

Enc: Cenobamate (Ontozry®) information for Community Pharmacies