South Yorkshire Integrated Care Board

South Yorkshire Integrated Care Board
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Our Ref: DC/NB

14th July 2025

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Barnsley Area Prescribing Committee Meetings on 14th May and 11th June 2025.

The main outcomes of the meetings were: -

Prescribing Guidelines

Oral Nutritional Supplements (ONS) Prescribing Guidelines in Primary Care: Adults aged 18 years and over [MINOR UPDATE]
This guideline has received a minor update as Aymes® Actagain 600 has been renamed **Aymes® Actagain 2.4 Daily**. Clinicians are advised to exercise particular care when prescribing as there is another Aymes product with a very similar name, namely Aymes® Actagain 2.4. Aymes Actagain 2.4 Daily and Aymes Actagain 2.4 are different products with different nutritional content.

Barnsley Wound Care Formulary 2025-2026 [UPDATED]
The updated Wound Care Formulary was received by the Committee and this has since been approved by the Wound Care Advisory Group.

Barnsley Lipid Management for Secondary Prevention of Cardiovascular Disease in Adults guidance [UPDATED]
This guideline has been updated in line with the NHS AAC Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD. The treatment targets / thresholds for secondary prevention reflect the NICE/QOF target: LDL-C of ≤ 2.0 mmol/L, or non-HDL-C of ≤ 2.6 mmol/L at least. JBS3 is still included for reference. Referral criteria for the secondary care lipid clinic (including conditions treated and exclusions) have also been added.

The guideline, along with the existing South Yorkshire lipid management pathway, can be accessed here.

South Yorkshire Integrated Medicines Optimisation Committee (IMOC) approved Prescribing Guidelines
The following South Yorkshire IMOC approved prescribing guidelines and medicines optimisation resources were received by the Committee:

- **Yorkshire and the Humber A Guide to Symptom Management in Palliative Care**
  A-Guide-to-Symptom-Management-in-Palliative-Care-v8-Approved-by-HNY-IPMOC-February-2024.pdf

This is an additional resource and is not intended to replace any local palliative care formularies.

- **Community Pharmacy England 'Where's my medicine?' patient information leaflets (B&W and colour versions)**
  https://cpe.org.uk/wp-content/uploads/2025/06/Medicines-supply-leaflet-June-2025-Colour.pdf
  https://cpe.org.uk/wp-content/uploads/2025/06/Medicines-supply-leaflet-June-2025-BW-version.pdf
  These may be useful when discussing stock shortages with patients. The medicines shortages section of the CPE website also includes other useful resources: https://cpe.org.uk/dispensing-and-supply/supply-chain/medicine-shortages/

- **SY ICB Position Statement on Tirzepatide for managing Overweight and Obesity**
  Tirzepatide_SYICB__Position_Statement_May_2025_V2.pdf
  Frequently asked questions for patients are also available https://southyorkshire.icb.nhs.uk/your-health/nices-announcement-tirzepatide-frequently-asked-questions-patients

- **South Yorkshire Pancreatic Enzyme Replacement Therapy (PERT) information:**
  Managing PERT Shortages: Creon® Alternative (Adults) – Imported Pangrol®:
  Pangrol_-OPS_information_V1.pdf
  PERT_-_Information_for_Patients_V1.0.pdf
  PERT_-OPS_New_Customer_Verification_Form_V12.pdf

- **South Yorkshire Vitamin D documents:**
  Vitamin D Management in Adults (including Pregnancy/ Breastfeeding) - Guidelines on the prevention, diagnosis, and management of vitamin D deficiency care:
  SYICB_Vitamin_D_Adults_Guidelines__V1.pdf
  SYICB_Vitamin_D_Adults_Management_Flow_Chart_-_V1.1.pdf (non-pregnant adults)
  SYICB_Vitamin_D_Pregnancy__Breastfeeding_Management_Flow_Chart__V1.pdf

  South Yorkshire Vitamin D Patient Information Leaflets:
  SY_Vitamin_D_Patient_Information_leaflet_V1.0.pdf
  SY_Pregnancy_Breastfeeding_Vitamin_D_Patient_Information_Leaflet_V1.0.pdf
  There are also short versions of the vitamin D leaflet (in English, Arabic, Punjabi, Slovak, Somali and Urdu) available on the South Yorkshire IMOC section of the ICB website (link below).

The links included above link to the latest version of the respective guideline at the time of writing. To ensure you are accessing the latest version, the guidelines can be found under the 'South Yorkshire IMOC Guidance Documents' blue drop down header tab, on the South Yorkshire IMOC section of the ICB website:
South Yorkshire Integrated Medicines Optimisation Committee :: South Yorkshire I.C.B

Amber G / Shared Care Guidelines

Barnsley Shared Care Guideline for Amiodarone [UPDATED]
This Shared Care Guideline has been updated with minor amendments and a link to the finalised version will be shared in due course.

Barnsley DMARDs Shared Care Guideline [MINOR UPDATES]
The DMARDs Shared Care Guideline has undergone minor updates:

- Addition of a link to the MHRA alert: Thiopurines and intrahepatic cholestasis of pregnancy (see MHRA Safety Roundup section below). The following information has been added: *Intrahepatic cholestasis of pregnancy (ICP) has been rarely reported in patients treated with azathioprine. Cholestasis of pregnancy associated with thiopurines tends to occur earlier in pregnancy than non*

drug-induced cholestasis of pregnancy, and elevated bile acid levels may not reduce with ursodeoxycholic acid. Pregnant women with significant itchiness without a rash, nausea or loss of appetite should contact Obstetrics and Gynaecology to discuss. O & G may then discuss with Rheumatology if ICP is suspected.

- Blood pressure and weight monitoring have been added to the 'routine monitoring' and 'primary care monitoring' sections in the leflunomide section.
- Information on sulfasalazine standard tablets have been added. Sulfasalazine standard tablets are not licensed for use in rheumatological conditions, unlike sulfasalazine enteric coated tablets. However off-label use of the plain tablets has been endorsed locally by the specialists at BHNFT and the Barnsley Area Prescribing Committee. Sulfasalazine standard release tablets are used where clinically appropriate in new patients and sulfasalazine enteric coated tablets are reserved for use when the plain tablets are considered unsuitable.

A link to the finalised version will be shared in due course.

Other

Barnsley Primary Care Medicines Optimisation Scheme 2025/26

The purpose of the Barnsley primary care Medicines Optimisation Scheme is to encourage the high quality, safe and cost-effective use of medicines across the patient pathway. In line with the priorities identified within the wider South Yorkshire Medicines Optimisation QIPP plan, the 2025/26 Barnsley scheme incorporates workstreams to help achieve efficiencies and ensure best value prescribing. A summary of these workstreams was received by the Committee. These are summarised in the table below along with the associated formulary changes which were supported by the Committee. Reviews will be undertaken in primary care in these workstream areas in line with the 2025/26 scheme.

Barnsley Formulary Updates

The Committee noted the traffic light classifications recently assigned by the South Yorkshire Integrated Medicines Optimisation Committee (IMOC) and agreed the following formulary updates:

Drug	Formulary Indication	Barnsley Formulary status (including traffic light classification)
Horizon Scanning May 2025 IMOC		
Clascoterone	Topical treatment of acne vulgaris in patients aged ≥12 years	Non-formulary grey 10 mg in 1g cream NICE TA in development
IMOC Sub-Group Agreed Traffic Light Listing April 2025		
Sildenafil brand: Viagra®	Erectile Dysfunction	Formulary grey Sildenafil generic for erectile dysfunction is formulary green
Tadalafil brand: Cialis®	Erectile Dysfunction	Formulary grey Tadalafil generic for erectile dysfunction is formulary green
IMOC Sub-Group Green Drugs June 2024 Part 1		
Cimetidine	H2-receptor antagonist	Formulary green (previously formulary grey)
Ciprofloxacin	Quinolone antibiotic	Formulary green (previously formulary grey) Refer to Primary Care Antimicrobial Guidelines: Antibiotic /Antimicrobial -Prescribing Guidelines - BEST
Esomeprazole	Proton Pump Inhibitor	Formulary green (previously formulary grey)
Brimonidine gel	Indicated for the symptomatic treatment of facial erythema of rosacea in adult patients	Formulary green (previously non-formulary grey) Rosacea | Health topics A to Z | CKS | NICE

Fluvastatin	Lipid management	Formulary green (previously formulary grey) Fluvastatin has a high cost in relation to other statins. Refer to CVS: Barnsley Lipid Management for Primary Prevention of CVD in Adults - BEST Fluvastatin 80mg prolonged-release tablets will remain non-formulary.
Folic acid	Folate-deficient megaloblastic anaemia, prevention of neural tube defects, prevention of methotrexate-induced side-effects, prophylaxis of folate deficiency	Formulary green (already formulary green) 1mg/ml oral solution will remain non-formulary due to the significantly high cost (Drug Tariff July 2025: folic acid 2.5mg/5ml x 150ml = £9.16, folic acid 1mg/ml oral solution x 150ml = £84.81)
IMOC May 2025		
Tirzepatide	Weight management indication	Formulary red (previously formulary grey) Tirzepatide_SYICB__Position_Statement_May_2025_V2.pdf
Zuclopenthixol acetate	For the initial treatment of **acute psychoses** including mania and exacerbation of chronic psychoses, particularly where a duration of effect of 2-3 days is desirable.	Non-formulary red
High Strength Sodium Fluoride toothpaste (containing 2800ppm (0.619%) or 5000ppm (1.1.%) sodium fluoride)	Prevention of dental caries	Formulary green (specialist recommendation) **only** when prescribing in line with the exceptions in the Prescribing of Medicines for the treatment of Dental Conditions on FP10 SY ICB Position Statement. A link to the South Yorkshire position statement will be shared in due course.
South Yorkshire Vitamin D Guidance (see links in prescribing guidelines section above)		
Colecalciferol 50,000IU capsules (Invita D3®)	For correction of Vitamin D level with high dose treatment/loading regimen in adults.	Formulary green (first line choice) Suitable in peanut/soya allergy, halal and kosher certified.
Colecalciferol 25,000IU tablets (Stexerol-D3®)	For correction of Vitamin D level with high dose treatment/loading regimen in adults. (also second line monthly preparation for vitamin D maintenance dosing in adults)	Formulary green (second line choice) Suitable in peanut/soya allergy, suitable for vegetarians, halal and kosher certified, gelatin free.
Colecalciferol 50,000IU /1ml oral solution 'snap and squeeze' (Invita D3®)	For correction of Vitamin D level with high dose treatment/loading regimen in adults.	Formulary green Suitable in peanut/soya allergy, suitable for vegetarians, halal and kosher certified, gelatin free.
Colecalciferol 800IU capsules (Invita D3®)	Vitamin D preparation for maintenance dosing in adults.	Formulary green (first line choice) Suitable in peanut/soya allergy, halal and kosher certified.
Colecalciferol 1000IU tablets (Stexerol-D3®)	Vitamin D preparation for maintenance dosing in adults.	Formulary green (second line choice) Suitable in peanut/soya allergy, suitable for vegetarians, halal and kosher certified, gelatin free.
Colecalciferol 2400IU/ml oral drops (Invita D3®)	Vitamin D preparation for maintenance dosing in adults.	Formulary green Suitable in peanut/soya allergy, suitable for vegetarians, halal and kosher certified, gelatin free. Note: 1ml contains 36 drops (6 drops provides 400 units) Licensed in pregnancy / breastfeeding, infants and children

Colecalciferol 25,000IU capsules (Invita D3®)	First line monthly vitamin D preparation for maintenance dosing in adults.	Formulary green For use in children refer to the Guideline for the Management of Children and Young Adults with suspected Vitamin D Deficiency in Primary Care. Suitable in peanut/soya allergy, halal and kosher certified.
Colecalciferol 800IU capsules (Fultium-D3®)	Vitamin D deficiency	Formulary green Licensed preparation for use in pregnancy Refer to the SY Vitamin D adult guidance for further information.
Colecalciferol 3200IU capsules (Fultium D3®)	Vitamin D deficiency	Licensed preparation for use in pregnancy Refer to the SY Vitamin D adult guidance for further information.
Barnsley Medicines Optimisation Scheme 2025/26 QIPP Workstreams [all workstreams are subject to future stock availability]		
Oestrogens, Topical (Estriol 1mg/g vaginal cream)	HRT	Estriol 0.1% vaginal cream has a significantly lower acquisition cost than estriol 0.01% vaginal cream and both deliver a 0.5mg dose of estriol due to the different applicator sizes Estriol 0.01% vaginal cream is non-formulary in Barnsley [MOS workstream: estriol 0.01% vaginal cream to estriol 0.1% vaginal cream]
Spironolactone 12.5mg tablets	Aldosterone antagonist	Half a 25mg tablet is more cost effective than a 12.5mg tablet [MOS workstream: spironolactone 12.5mg tablet to half a 25mg tablet]
Venlafaxine XL	Antidepressant	Vencarm® XL capsules are the cost-effective brand of choice for venlafaxine XL 35.7mg, 75mg, 150mg and 225mg tablets and capsules in primary care in Barnsley [MOS workstream: venlafaxine XL to Vencarm®]
Sertraline 25mg tablets	SSRI Antidepressant	Formulary grey (25mg strength tablets) Half a 50mg sertraline tablet is more cost effective than a 25mg tablet [MOS workstream: sertraline 25mg tablet to half a 50mg tablet]
Sodium Picosulfate	Stimulant laxative	It is more cost effective to prescribe sodium picosulfate 5mg/5ml solution as Dulcolax® in primary care [MOS workstream: sodium picosulfate 5mg/5ml solution to Dulcolax®]
Riluzole	Amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND)	Riluzole has an amber classification It is more cost effective to prescribe riluzole as orodispersible tablets [MOS workstream: riluzole tablets to riluzole orodispersible tablets]
Dorzolamide preservative free eye drops	Treatment of elevated intra-ocular pressure	If preservative free dorzolomide 20mg/ml eye drops are indicated, the 5ml bottle is a more

		cost effective formulation than the 0.2ml unit doses [MOS workstream: dorzolamide 20mg/ml preservative free unit dose eye drops to dorzolamide 20mg/ml preservative free (5ml bottle)]
Cetirizine oral solution	Antihistamine	If cetirizine oral solution is indicated, it is more cost effective to prescribe as the brand Zirtek® Allergy. [MOS workstream: if a prescription is indicated, cetirizine oral solution to Zirtek® Allergy]
Azithromycin 250mg capsules	Macrolide antibiotic	Tablets are more cost effective than capsules [MOS workstream: azithromycin 250mg capsules to azithromycin 250mg tablets]
Glyceryl trinitrate spray	Angina pectoris	The most cost effective GTN spray formulation is the glyceryl trinitrate 400micrograms/dose pump sublingual spray 180 dose [MOS workstream: GTN spray to GTN pump spray 180 dose]
Nitrofurantoin tablets	Lower urinary tract infections	Capsules are more cost-effective than tablets [MOS workstream: nitrofurantoin tablets to capsules]
Nebivolol 1.25mg tablets	Hypertension and heart failure	Half a 2.5mg tablet is more cost effective than a 1.25mg tablet. [MOS workstream: nebivolol 1.25mg tablet to half a 2.5mg tablet]
Fluticasone propionate nasal spray	Allergic rhinitis	It is more cost effective to prescribe fluticasone propionate nasal spray as the brand Nasofan® [MOS workstream: fluticasone propionate nasal spray to Nasofan®]
Metformin oral solution	Type 2 diabetes mellitus	When the patient is unable to swallow tablets, powder sachets and the 500mg/5ml oral solution are first and second line options respectively. The oral solution is reserved for patients in whom the sachets are not appropriate (for example, fluid restricted patients). The 1g/5ml x 150ml oral solution is less cost effective – it has a non-formulary status in Barnsley. [MOS workstream: metformin oral solution to metformin powder sachets]
Other MOS QIPP workstreams (existing formulary choices detailed in brackets)		Buprenorphine weekly patches (Sevodyne®) Fentanyl patches (Opiodur®) DOACs (generic rivaroxaban or generic apixaban) Calcium and colecalciferol (Calci-D®) Blood glucose and ketone test strips (Barnsley test strip guidelines) Beclometasone and formoterol MDI (Luforbec®) Budesonide and formoterol DPI (Fobumix® has a lower acquisition cost than Symbicort® and is the first line budesonide/formoterol DPI on the Barnsley formulary)

Other		
Progesterone 100mg capsules (micronised progesterone)	Indicated for adjunctive use with oestrogen in post-menopausal women with an intact uterus, as hormone replacement therapy (HRT).	Formulary green Generic prescribing of 100mg micronised progesterone capsules is more cost-effective than prescribing as Utrogestan®
Estradiol 10 microgram vaginal tablets	Treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women.	Formulary green Generic prescribing of estradiol 10 microgram vaginal tablets is more cost-effective than prescribing as Vagirux®.
Metronidazole 0.75% gel (Anabact®)	For the treatment of acute inflammatory exacerbation of rosacea. The deodorisation of malodorous fungating tumours, gravitational ulcers and decubitus ulcers.	Formulary green Anabact® (metronidazole 0.75% gel) is now licensed for the treatment of acute inflammatory exacerbation of rosacea. However Acea® (metronidazole 0.75% gel) which is also licensed for rosacea has a low acquisition cost (based on 40g pack size). When metronidazole 0.75% gel is prescribed for the treatment of acute inflammatory exacerbation of rosacea: First line: Acea® gel Second line: Anabact® gel
Relugolix + estradiol + norethisterone (Ryeqo®)	For treating symptoms of endometriosis	Formulary red for endometriosis. Relugolix–estradiol–norethisterone (Ryeqo®) remains formulary amber for uterine fibroids in line with the existing SY shared care guideline.
Calcipotriol 50micrograms/g with betamethasone 0.5mg/g cream	Mild to moderate psoriasis vulgaris, including scalp psoriasis, in adults.	Formulary green Generic calcipotriol/betamethasone **cream** is the first line calcipotriol/betamethasone preparation as it has the lowest acquisition cost

MHRA Safety Roundup

The MHRA have launched a new safety bulletin, the MHRA Safety Roundup. This will be published at the end of each month and provides a summary of all the MHRA safety alerts for the past month including drug safety updates (DSU), device safety information (DSI), national patient safety alerts, recalls and medicines notifications, and letters sent to healthcare professionals.

Healthcare professionals need to subscribe to receive the new MHRA Safety Roundup - https://subscriptions.mhra.gov.uk/accounts/UKMHRA/signup/45372. Email alerts for MHRA Drug Safety Updates will continue to be sent via email alert to existing subscribers as they are published.

Recent MHRA Drug Safety Roundups can be accessed at the following links:
April_Safety_Roundup_Final.pdf
May_Safety_Roundup_Final.pdf

Issues relating to primary care:

Fezolinetant▼(Veoza): risk of liver injury; new recommendations to minimise risk
Fezolinetant treatment is associated with a risk of drug induced liver injury. New recommendations have been introduced to minimise this risk. Liver function should be monitored before and during treatment in all patients taking fezolinetant. Fezolinetant should be avoided in patients with known liver disease or at a higher risk of liver disease. *Fezolinetant has a non-formulary grey drug classification on the Barnsley formulary*

Advice for Healthcare Professionals:

- cases of serious liver injury with elevated transaminases, bilirubin and signs and symptoms of hepatic dysfunction have been reported during treatment with fezolinetant. These were generally reversible on discontinuation of therapy
- avoid fezolinetant in patients with known liver disease or patients at higher risk for liver disease
- treatment with fezolinetant must not be initiated if serum alanine aminotransferase (ALT) or serum aspartate aminotransferase (AST) levels are ≥2x the upper limit of normal or if total bilirubin levels are ≥2x the upper limit of normal
- treatment with fezolinetant must be discontinued if:
    - transaminase elevations are ≥3x the upper limit of normal with: total bilirubin >2x the upper limit of normal OR if patients develop symptoms of liver injury
    - transaminase elevations >5x the upper limit of normal
- perform liver function tests, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum alkaline phosphatase (ALP) and serum bilirubin (total and direct), prior to treatment initiation, monthly during the first 3 months of treatment and periodically thereafter based on clinical judgment
- liver function tests must also be performed when signs or symptoms suggestive of liver injury occur
- monitoring should be maintained until liver function tests have normalised
- patients should be advised to seek immediate medical attention if they develop any sign or symptoms of liver injury, including fatigue, pruritus, jaundice, dark urine, pale faeces, nausea, vomiting, decreased appetite and/or abdominal pain
- a Direct Healthcare Professional Communication (DHPC) has been disseminated alongside this Drug Safety Update
- report suspected adverse drug reactions associated with fezolinetant via the Yellow Card scheme

Advice for Healthcare Professionals to Provide to Patients:

- fezolinetant is used for the treatment of moderate to severe vasomotor symptoms, including hot flushes and night sweats, associated with the menopause
- there have been cases of liver problems in people taking fezolinetant, which were generally reversible following discontinuation of treatment
- all patients will now have their liver function tested before and during treatment
- you will have a blood test to check your liver function before you start taking fezolinetant. This will be repeated monthly during the first 3 months of treatment and then afterwards depending on when your doctor deems appropriate
- seek medical attention immediately if you develop symptoms suggesting a problem with your liver. These include tiredness, itching, yellowing of the skin and eyes, dark urine, light-coloured stools, feeling or being sick, loss of appetite or stomach pain
- always read the leaflet that is provided alongside your medicine, which contains information about taking fezolinetant and a full list of known possible side effects
- report suspected adverse drug reactions to the Yellow Card scheme

Short-acting beta 2 agonists (SABA) (salbutamol and terbutaline): reminder of the risks from overuse in asthma and to be aware of changes in the SABA prescribing guidelines

Healthcare professionals and patients are reminded of the risk of severe asthma attacks and increased mortality associated with overuse of SABA with or without anti-inflammatory maintenance therapy in patients with asthma. Healthcare professionals should be aware of the change in guidance that no longer recommends prescribing SABA without an inhaled corticosteroid.

Advice for Healthcare Professionals:

- excessive use of SABA to relieve acute asthma symptoms may mask progression of the underlying disease and contribute to an increased risk of severe and potentially life-threatening asthma exacerbations
- do not prescribe SABA to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid (see Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) NICE guideline [NG245], 2024)
- ensure all patients with asthma receive optimal anti-inflammatory maintenance therapy even when their asthma is well controlled and that treatment is individualised to the patient
- review and adjust asthma treatment in patients who take more than twice weekly “as needed” SABA
- urgently review patients where there has either been an increase in the number of prescriptions requested for SABA reliever inhalers or a failure to collect prescribed anti-inflammatory maintenance treatment

- anti-inflammatory reliever (AIR) therapy and maintenance and reliever therapy (MART) are recommended alternatives for people over 12 years of age with poorly controlled asthma
- report suspected adverse drug reactions via the Yellow Card scheme

Advice for Healthcare Professionals to Provide to Patients:

- seek urgent medical assistance if worsening asthma symptoms (for example, chest tightness, wheezing, coughing, or difficulty breathing) are not relieved by using the asthma reliever medicines prescribed by a healthcare professional to be used during an asthma attack
- if a blue inhaler is prescribed as the asthma reliever medication to be used during an asthma attack, a separate asthma preventer therapy will always be prescribed for regular daily use as well
- use the asthma anti-inflammatory maintenance medication as prescribed by a healthcare professional even when asthma is well-controlled and the blue inhaler is rarely or never needed
- if the blue inhaler does not have a dose counter, manually track the doses used and ensure you always have access to a spare inhaler before your current inhaler runs out or expires
- follow your agreed asthma plan if you have one or ask your healthcare professional for an asthma review if the prescribed asthma blue reliever inhaler is needed more than twice a week
- your healthcare professional can provide advice on recommended alternative treatments (to the blue inhaler) for people over 12 years of age with poorly controlled asthma
- report suspected adverse drug reactions to the Yellow Card scheme

Thiopurines and intrahepatic cholestasis of pregnancy

Intrahepatic cholestasis of pregnancy (ICP) has been rarely reported in patients treated with azathioprine products and is believed to be a risk applicable to all drugs in the thiopurine class (azathioprine, mercaptopurine and tioguanine). Cholestasis of pregnancy associated with thiopurines tends to occur earlier in pregnancy than non drug-induced cholestasis of pregnancy, and elevated bile acid levels may not reduce with ursodeoxycholic acid.

Key Advice for Healthcare Professionals:

- cholestasis of pregnancy has rarely been reported in association with azathioprine therapy
- this risk is believed to also apply to the other thiopurine drugs, mercaptopurine and tioguanine
- it may occur earlier in pregnancy than non drug-induced cholestasis of pregnancy, and it may not respond to ursodeoxycholic acid
- withdrawal or dose reduction of the thiopurine drug may improve liver function tests
- remain vigilant to signs and symptoms of ICP in pregnant patients taking thiopurines and discuss any concerns with clinicians managing the patient's immunosuppressant therapy and a hepatologist, as necessary
- if cholestasis of pregnancy occurs, a case-by-case assessment is required to determine the appropriate course of action. Consider the risks and benefits of remaining on the product against the risks and benefits of stopping.
- in patients with ICP, measure serum bile acids to identify pregnancies at particular risk of spontaneous preterm birth (≥40uM) or stillbirth (non-fasting serum bile acids ≥100uM)

Key Advice for Healthcare Professionals to Provide to Patients:

- talk to your doctor or midwife immediately if you experience symptoms of cholestasis of pregnancy which include intense itching without a rash, nausea, and loss of appetite
- do not stop taking your medication unless advised to do so by your doctor or midwife

Kaftrio▼ (Ivacaftor, tezacaftor, elexacaftor): risk of psychological side effects

Psychological side effects such as anxiety, low mood, sleep disturbance, poor concentration, and forgetfulness have been infrequently reported in people with cystic fibrosis treated with Kaftrio. Healthcare professionals should advise patients and their caregivers that, while the risk is small, they should be alert to changes in mood and behaviour and, if they occur, to seek medical advice as soon as possible.

Red drug classification, specialist drugs should be recorded on the clinical system in such a way that they cannot be inadvertently issued in primary care

Key Advice for Healthcare Professionals:

- there is a small increase in the risk of psychological side effects in people with cystic fibrosis treated with Kaftrio

- there is also an indirect risk of psychological side effects from difficulty adjusting to Kaftrio-related improvements to physical health and quality of life
- individuals with life-limiting conditions such as cystic fibrosis also have an increased background risk of developing poor mental health
- advise patients and their caregivers to be alert to the development of psychological side effects usually within the first three months of treatment including anxiety or low mood, sleep disturbance, poor concentration, or forgetfulness. The side effects may occur in people who have no history of these problems
- in some children, the psychological side effects may manifest themselves as persistent changes in behaviour while taking Kaftrio. Signs of this could include being more disruptive or difficult to manage
- discuss the benefit-risk balance of Kaftrio treatment with the patient or caregiver and consider treatment discontinuation if a patient develops these symptoms
- report suspected adverse drug reactions associated with Kaftrio on a Yellow Card

Key Advice for Healthcare Professionals to Provide to Patients:

- Kaftrio is a medicine used for the treatment of cystic fibrosis
- there have been infrequent reports in patients of all ages of low or altered mood, anxiety, problems with sleep, concentration, and/or forgetfulness
- some children, while taking Kaftrio, may notice persistent changes in the way they feel and/or act that are different to their usual patterns. This includes being more disruptive or difficult to manage
- these events usually happen within the first three months after starting treatment with Kaftrio and may occur in people who have no history of these problems
- it can be difficult for patients to know if their symptoms relate to Kaftrio or to something else. For some people, these changes can be associated with adjusting to the improvements that Kaftrio has on their physical health and their quality of life
- for many, the symptoms may not last long, but others will continue to experience them whilst they take Kaftrio
- you may not notice some changes in your mood and behaviour so it is very important to tell your friends and family that you are taking this medicine and that it can have psychological side effects. Others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about
- talk to your doctor or cystic fibrosis team as soon as possible if you or your family or friends notice signs or symptoms of psychological side effects. Your doctor will advise on the most appropriate action to take
- report suspected adverse drug reactions associated with Kaftrio on a Yellow Card

Kind Regards

Deborah Cooke
Senior Pharmacist [Strategy and Delivery - Barnsley & Clinical Effectiveness]

cc: Medicines Optimisation Team (Barnsley Place)
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Area Prescribing Committee Members (Secretary to the APC to circulate)
Local Medical Committee (Secretary to the LMC to circulate)
Heidi Taylor, South Yorkshire ICB
Ashley Hill, South Yorkshire ICB (IMOC Secretary)