PRESCRIPTION PAD

NORTH CUMBRIA HEALTH & CARE

Medicines Optimisation Committee newsletter

August 2019 No. 01

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Primary Care News	Secondary Care News	Updates from the MHRA & NICE	North of Tyne APC and formulary update
North of Tyne Branded prescribing guideline Freestyle Libre prescribing Liothyronine prescribing Updated COPD Inhaler decision tool Updated Management of Exacerbations of COPD guidance Community Pharmacy Cumbria update on MDS supplies Melatonin licensed 1mg/ml solution Ertugliflozin – TA572 & TA583	Non medical prescribing guideline policy New trust wide prescription chart Controlled Drugs Accountable Officer (CDAO) update Adoption of nationally recognised chemotherapy consent forms Patient Group Directions (PGDs) Alcohol detoxification guideline for mental health wards Antibiotic prophylaxis against infective endocarditis	Valproate Update April 2019 Drug Safety Update July 2019 - Febuxostat - Tocilizumab - Rivaroxaban NICE Clinical Guidelines: NG128: Stroke and transient ischaemic attack in over 16's: diagnosis and initial management NG131: Prostate cancer: diagnosis and management	APC decision summary 9th July 2019

Primary Care News

Special mention: North Cumbria Medicines Optimisation Committee (formerly the North Cumbria APC) would like to thank **Dr Andrea Mulgrew** (Maryport Health Services) for all her work over the past years with North Cumbria APC and now the North Cumbria MOC. We hope you enjoy your retirement.

North of Tyne Branded Prescribing Guideline	North Cumbria has now adopted the North of Tyne Branded Prescribing Guideline. This is an updated UKMi document which shows which drug groups should be prescribed by brand for reasons of continuity and patient safety**. Our main focus will still remain on generic prescribing unless there is a clinical reason to do differently.** https://medicines.necsu.nhs.uk/download/north-of-tyne-and-north-cumbria-brand-name-prescribing-guidance/
Freestyle Libre prescribing	From the 1st April 2019 NHSE agreed that Freestyle Libre would become more widely available to Type 1 Diabetics. NTAG updated their guidance for its prescribing in both primary and secondary care. The North East and North Cumbria then produced a position statement for use across the region. This provides letters that have been adopted for use across North Cumbria which should be used by Secondary care when transferring patients to Primary Care. https://medicines.necsu.nhs.uk/download/nenc-freestyle-libre-position-statement/
Liothyronine prescribing	Liothyronine now has a GREEN+ RAG rating on the North of Tyne, Gateshead and North Cumbia formulary. RMOC (Regional Medicines Optimisation Committee) has now updated their guidance (June 19). We have now adopted this guidance and the GREEN+ RAG rating across North Cumbria and we are working with secondary care on a North Cumbria Prescribing Guideline which will set out the clear responsibilities that will need to be fulfilled before a new patient can be started on Liothyronine. We will share this guidance once completed.
Updated COPD inhaler decision tool	The North Cumbria COPD inhaler decision tool has now been updated. This now follows the North of Tyne formulary and includes triple therapy devices. https://medicines.necsu.nhs.uk/download/copd-inhaler-decision-tool-north-cumbria/

Management of acute exacerbations of COPD	The management of acute exacerbations of COPD has also been updated for use in Primary Care. This now follows NICE guidelines when supplying 5 days of antibiotics. https://medicines.necsu.nhs.uk/download/management-of-acute-exacerbation-of-copd-north-cumbria/
Community Pharmacy update on MDS supplies	Community Pharmacy Cumbria (formerly the LPC) have updated their guidance regarding the supply of MDS (dosette trays) by community pharmacies. Community Pharmacies may now start to charge for MDS for patients that do not fall under the Equality Act 2010. This means is that if a patient with an MDS is trying to manage themselves at home on their own then they will still be eligible for a free MDS, if a patient has carers going in to give them their meds then they may not be entitled to a free MDS. The community pharmacist will now perform an assessment on each patient to see if they are eligible for free MDS, it is no longer a request that a GP practice can make for free MDS. https://www.communitypharmacycumbria.org/wp-content/uploads/2019/07/Community-Pharmacy-and-MDS-July-2019.pdf
Melatonin Licensed 1mg/ml oral solution	A new licensed product of 'Melatonin 1mg/1ml oral solution' is now available, licensed only for the use of 'short term treatment of jet-lag in adults'. However, the manufacturer has not tested this in children and adolescents and do not deem it safe for use in under 18s. Until further information is available, if a third line liquid is required for a child, the licensed product should not be used off-label. Specials laboratories and community pharmacies may request proof of clinical need for patients to be prescribed unlicensed products. Prescribers are recommended to communicate the requirement for a patient to receive the unlicensed melatonin formulation, by adding a note on the prescription (for example patient note or in the directions) or separate letter, outlining the clinical need.

Ertugliflozin TA572 **GREEN +**	Ertugliflozin as monotherapy is recommended as an option for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if: • a dipeptidyl peptidase 4 (DPP-4) inhibitor would otherwise be prescribed and a sulfonylurea or pioglitazone is not appropriate. • Ertugliflozin in a dual-therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if: • a sulfonylurea is contraindicated or not tolerated or the person is at significant risk of hypoglycaemia or its consequences.
Ertugliflozin TA583 **GREEN +**	Ertugliflozin with metformin and a dipeptidyl peptidase-4 (DPP-4) inhibitor is recommended as an option for treating type 2 diabetes in adults when diet and exercise alone do not provide adequate glycaemic control, only if: • the disease is uncontrolled with metformin and a DPP-4 inhibitor, and a sulfonylurea or pioglitazone is not appropriate. • If patients and their clinicians consider ertugliflozin to be 1 of a range of suitable treatments, including canagliflozin, dapagliflozin and empagliflozin, the least expensive should be chosen.

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Secondary Care News

Non- Medical Prescribing Policy	A system-wide Non-Medical Prescribing Policy is under development. Paul Fieldhouse is the Joint Trust NMP lead.
New trust-wide medicines chart	A revised medicines chart will be launched soon. It is the pre-cursor to electronic prescribing which will be implemented within the next year.
Controlled Drugs Accountable Officer (CDAO)	The Accountable Officer (AO) for Controlled Drugs for Cumbria Partnership NHS Foundation Trust and North Cumbria University Hospitals NHS Trust is Paul Fieldhouse (Clinical Director Pharmacy and Medicines Optimisation) Paul.fieldhouse@ncuh.nhs.uk The CDAO is responsible for all aspects of the safe and secure management of controlled drugs.
Adoption of nationally recognised chemotherapy consent forms	North Cumbria has adopted the nationally recognised SACT (Systemic Anti-Cancer Chemotherapy) consent forms. The new forms have been developed nationally and are specific to each chemotherapy regimen. The forms are held centrally and are updated for all new regimens with details of side effects.
Patient Group Directions (PGDs)	A Joint Trust PGD Policy has been ratified and is available on the Trust intranet. A new PGD Approval Group has been set up to review existing PGDs and new requests. Contact Venessa Echanique for more details Venessa.echanique@ncuh.nhs.uk
Alcohol detoxification guideline for mental health wards	This updated guideline has been approved for use by the Mental Health Care Group Governance Committee and also the MOC. All staff will be trained in the use of the symptoms trigger scale as mentioned in the guideline.
Antibiotic prophylaxis against infective endocarditis	Co-developed with British Dental Association, this tool is a data collection sheet accompanied by a comprehensive guide enabling dental prescribers to complete a clinical audit of their antimicrobial prescribing and/or their overall management of dental infections. http://www.sdcep.org.uk/published-guidance/antibiotic-prophylaxis/

Updates from the MHRA & NICE

Valproate medicines and serious harms in pregnancy: New Annual Risk Acknowledgement form and clinical guidance from professional bodies to support compliance with the Pregnancy Prevention Programme

(Drug safety update April 19)

Women of childbearing potential taking Valproate are now being referred to specialists for the Pregnancy Prevention Programme (PPP).

The updated Annual Risk Acknowledgement Form should be used during annual specialist review of all women and girls of childbearing potential on valproate medicines (irrespective of indication).
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/794114/Valp-ARAF-March-2019.pdf

Advice for healthcare professionals:

• use the revised Annual Risk Acknowledgement Form (version dated March 2019) at initiation and annual review of all girls and women of childbearing potential on valproate medicines (irrespective of indication)
• specialists should comply with guidance on the form if they consider there to be compelling reasons to indicate their patient is not at risk of pregnancy, including the need to document reasons for this and for the patient or responsible person to sign to confirm these are correct
• if the absence of pregnancy risk may change (for example, the patient is pre-menarchal), the date for the next annual discussion of the risks must be documented and the patient or the patient's family or caregivers asked to contact the prescriber rapidly if the situation changes
• there is no safe dose of valproate that can be used in pregnancy,

NICE guidance summary

To support healthcare professionals to understand their clinical responsibilities for valproate, NICE has produced a summary of their guidance and safety advice.
https://www.nice.org.uk/guidance/cg137/resources/valproate-in-children-young-people-and-adults-summary-of-nice-guidance-and-safety-advice-pdf-6723784045

Pan-college guidance

Experts from 13 national healthcare bodies, including 7 Royal Colleges, have produced clinical guidance to support healthcare professionals involved in the care of women on valproate. The 'pan-College' guidance advises on the more challenging issues that clinicians across primary and specialist care might encounter in daily practice. These include transition from paediatric to adult services, competence to consent to treatment, and confidentiality https://www.rcgp.org.uk/about-us/news/2019/march/thirteen-uk-healthcare-bodies-launch-pragmatic-guidance-on-valproate-use.aspx

Febuxostat (Adenuric) – Increased risk of cardiovascular death and all cause mortality in clinical trials in patients with a history of major cardiovascular disease **(Drug safety update July 19)**	Avoid treatment with febuxostat in patients with pre-existing major cardiovascular disease (for example, myocardial infarction, stroke, or unstable angina), unless no other therapy options are appropriate. Findings from a phase 4 clinical study (the CARES study) in patients with gout and a history of major cardiovascular disease show a higher risk for cardiovascular-related death and for all-cause mortality in patients assigned to febuxostat than in those assigned to allopurinol. **Advice for healthcare professionals:** • avoid treatment with febuxostat in patients with pre-existing major cardiovascular disease (for example, myocardial infarction, stroke, or unstable angina), unless no other therapy options are appropriate. • note the clinical guidelines for gout (see below), which recommend treatment with febuxostat only when allopurinol is not tolerated or contraindicated • report suspected adverse drug reactions to febuxostat on a Yellow Card
Tocilizumab (RoActemra) – Rare risk of serious liver injury including cases requiring transplantation **(Drug safety update July 19)**	Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be measured before starting treatment with tocilizumab and monitored every 4–8 weeks for the first 6 months of treatment followed by every 12 weeks thereafter. Serious liver injury has been reported on treatment with tocilizumab from 2 weeks to more than 5 years after initiation. **Advice for healthcare professionals:** • rare but serious cases of drug-induced liver injury, including acute liver failure and hepatitis, have been reported in patients treated with tocilizumab; some cases required liver transplantation • advise patients to seek medical help immediately if they experience signs and symptoms of liver injury, such as tiredness, abdominal pain, and jaundice • monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels at initiation, every 4–8 weeks during the first 6 months of treatment, and every 12 weeks thereafter in patients with rheumatological indications • exercise caution when considering treatment initiation in patients with ALT or AST higher than 1.5-times the upper limit of normal (ULN); initiation of treatment is not recommended in patients with ALT or AST higher than 5-times the ULN (see table below) • if liver enzyme abnormalities are identified, consult the dose modifications recommended, which have not changed (see below)
Rivaroxaban (Xarelto) – Reminder that 15mg and 20mg tablets should be taken with food. **(Drug safety update July 19)**	MHRA has received a small number of reports suggesting lack of efficacy (thromboembolic events) in patients taking 15 mg or 20 mg rivaroxaban on an empty stomach; remind patients to take 15 mg or 20 mg rivaroxaban tablets with food. **Advice for healthcare professionals:** • remind patients to take rivaroxaban 15 mg or 20 mg tablets with food • for patients who have difficulty swallowing, tablets can be crushed and mixed with water or apple puree immediately before taking; this mixture should be immediately followed by food • rivaroxaban 2.5 mg and 10 mg tablets can be taken with or without food • report suspected drug reactions, including any suspected events associated with lack of efficacy to rivaroxaban, on a Yellow Card

Updates from NICE

NG128: Stroke and transient ischaemic attack in over 16's: diagnosis and initial management May 2019	This guideline covers interventions in the acute stage of a stroke or transient ischaemic attack (TIA). It offers the best clinical advice on the diagnosis and acute management of stroke and TIA in the 48 hours after onset of symptoms. Note: **Initial management of suspected and confirmed TIA** 1.1.4 Offer aspirin (300 mg daily), unless contraindicated, to people who have had a suspected TIA, to be started immediately. https://www.nice.org.uk/guidance/ng128
NG131: Prostate cancer: diagnosis and management May 2019	This guideline covers the diagnosis and management of prostate cancer in secondary care, including information on the best way to diagnose and identify different stages of the disease, and how to manage adverse effects of treatment. It also includes recommendations on follow-up in primary care for people diagnosed with prostate cancer. https://www.nice.org.uk/guidance/ng131

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North of Tyne APC and formulary update

North of Tyne, Gateshead and North Cumbria APC website: http://www.northoftyneapc.nhs.uk/
North of Tyne, Gateshead & North Cumbria Formulary: http://northoftyneandgatesheadformulary.nhs.uk/default.asp

Product	Decision			Comments/notes
	Approved	Refused	Deferred	
New Product Requests				
13C-Methacetin 4mg/ml IV injection (LiMAxetin®)	✓ R			13C-Methacetin (LiMAxetin) is used with the LiMAx non-invasive breath test for the quantitative assessment of liver capacity in adults undergoing for liver surgery. The dose of 13C-methacetin is 2mg/kg as an IV bolus per test, a maximum of one test per day is permitted. 13C-methacetin is metabolised to paracetamol and carbon dioxide. The resulting exposure to paracetamol is in the region of 100 mg to 200 mg per day; this is several times lower than the therapeutic dose of IV paracetamol in adults and is therefore considered low risk. **Decision:** The request for 13C-Methacetin 4mg/ml IV injection (LiMAxetin®) was approved for the testing of liver function capacity.
Strontium ranelate (Aristo®)	✓ R			Strontium ranelate was previously included in the formulary but was withdrawn from the market in 2017 due to concerns around cardiovascular toxicity and venous thromboembolism. A new product, Aristo® has been brought to the market as a treatment option for severe osteoporosis in postmenopausal women or adult men at high risk of fracture, for whom other osteoporosis treatments are contraindicated or not tolerated. The committee recognised that strontium had a role in a small number of patients. **Decision: Approved.** Strontium ranelate (Aristo®), was approved as a RED drug, with prescribing retained in the hospital setting by specialists, to allow for careful cardiovascular monitoring.
New formulations & extensions to use				
Budesonide 1 mg orodispersible tablets (Jorveza®)			✓	Jorveza® (Budesonide 1 mg orodispersible tablets) is currently going through a NICE TA process which is due to be published in October, it was therefore agreed to defer until that time. **Decision:** The request for Jorveza® was deferred until the NICE TA has been published
Eslicarbazepine 50mg/ml suspension	✓ G+			The neurology team at NuTH has requested that eslicarbazepine 50mg/ml suspension is added to formulary as an alternative formulation for a small cohort of patients with swallowing difficulties. The cost difference for the suspension, compared to the tablets, is minimal. **Decision:** The request for eslicarbazepine was approved for use by the neurology service for a small cohort of patients with swallowing difficulties

Lisdexamfetamine	✓			NICE guidance has been updated and elevates lisdexamfetamine above dexamfetamine, taking it from third to second line. A Shared care agreement has been agreed and a request to update the formulary accordingly has been received. **Decision:** Formulary to be updated accordingly.
Fosfomycin sachets – request for status change from green plus to green.	✓ G			New NICE guidance places fosfomycin as an alternative treatment for UTI in patients where the first line treatments have failed, therefore it has been requested that the status is changed to Green. The advice of the microbiology teams was sought and they agree this is an appropriate change. **Decision: Approved** Fosfomycin sachets – status change to green

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