NHS Cumbria Clinical Commissioning Group

PRESCRIPTION PAD

The Newsletter of the Cumbria Area Prescribing Committee

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All Medicines Optimisation guidance, Shared Care Guidelines, PGDs and other resources can now be found on the NECS Medicines Optimisation Website. http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

Clinical Policy and Formulary News

Leflunomide Shared Care Protocol updated	The shared care protocol for leflunomide has been updated. Changes include definitions of stable dose and bloods, strengthening of the requirements for both secondary and primary care to give advice on contraception for both men and women whilst taking leflunomide, for two years after stopping and during washout. Advice on action to be taken when test results are out of range has been clarified. Available at http://medicines.necsu.nhs.uk/cumbria-shared-care-protocols/
Diazepam 10mg tablets for treatment of substance dependence	The Lothian formulary has been updated, Chapter 4 CNS (4.10,f) states prescribers should not initiate new maintenance benzodiazepine prescriptions for the treatment of substance dependence. Diazepam 10mg tablets should not normally be prescribed. The 2mg tablets strength tablets allow for easier reduction regimes.
Naloxone Patient Safety Alert from NHSE – October 15	NHSE issued a Stage 2 PAS for all organisations providing NHS funded care where naloxone is prescribed, dispensed and/or administered highlighting the resources available to organisation to implement the Stage 1 alert issued in November 2014. Naloxone is a highly effective antidote for opioids and opiates and its use is potentially life-saving in many circumstances. It is used across a range of care settings where opioid and opiate use is common, and for a number of scenarios that range from management of drug misuse and dependence to the provision of palliative care. However, as with any drug, its use may also pose risks against which the benefits of treatment need to be weighed. Giving too much naloxone can cause acute withdrawal syndrome (AWS) which is undesirable and unpleasant; other effects, which in some circumstances can be potentially life-threatening in themselves, are also possible. Appropriate dosing is complex and the resources support providers to develop appropriate local protocols and training. Available at https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/10/psa-naloxone-stage2.pdf
Water for irrigation for home ventilation patients	NHS England has reminded practices with patients under the care of the North East Assisted Ventilation Service that they should prescribe water for home ventilation for those patients who require it due to the severity of the condition and the specific device used. To be compatible with the device, practices must prescribe as: "**Water for infusion 1 litre bag**" for additional clarity the brand name "**Viaflo**" should be added to the prescription. This Baxter product is widely available from pharmaceutical wholesalers with the product code 'FE0304'

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NG20: Coeliac Disease: Recognition, assessment and management. September 2015

Nice has issued guidance on the recognition, assessment and management of Coeliac disease. https://www.nice.org.uk/guidance/ng20
The full list of recommendations can be found in the guideline. There are several key priorities for implementation which are relevant for primary care.

Recognition

Offer serological testing for coeliac disease to first degree relatives of people with coeliac disease and people with any of:

- Persistent unexplained abdominal or gastrointestinal symptoms
- Faltering growth
- Prolonged fatigue
- Unexpected weight loss
- Severe or persistent mouth ulcers
- Unexplained iron, vitamin B12 or folate deficiency
- Type 1 diabetes, at diagnosis
- Autoimmune thyroid disease, at diagnosis
- Irritable bowel syndrome (in adults)

For people undergoing investigations:

- Explain that any test is accurate only if a gluten-containing diet is eaten during the diagnostic process **and**
- Advise the person not to start a gluten-free diet until diagnosis is confirmed by a specialist, even if the results of serological testing are positive

Monitoring

Offer an annual review to people with coeliac disease which should include:

- Measurement of weight and height
- Symptom review
- Consider the need for assessment of diet and adherence to the gluten-free diet
- Consider the need for specialist dietetic and nutritional advice

Non-responsive and refractory coeliac disease

For people with coeliac disease who have persistent symptoms despite advice to exclude gluten from their diet, consider:

- Review the certainty of the original diagnosis
- Refer the person to a specialist dietician to investigate continued exposure to gluten
- Investigate potential complications or co-existing conditions that may be causing persistent symptoms, such as irritable bowel syndrome, lactose intolerance, bacterial overgrowth, microscopic colitis or inflammatory colitis

Diagnose refractory coeliac disease if the original diagnosis of coeliac disease has been confirmed, and exposure to gluten and any coexisting conditions have been excluded as the cause of continuing symptoms

Consider prednisolone for the initial management of the symptoms of refractory coeliac disease in adults while waiting for specialist advice

	Information and support A healthcare professional with a specialist knowledge of coeliac disease should tell people with a confirmed diagnosis of coeliac disease (and their family members or carers where appropriate) about the importance of a gluten-free diet and give them information to help them follow it, including; • Information on which types of food contain gluten and suitable alternatives, including gluten-free substitutes • Explanations of food labelling • Information sources about gluten-free diets, recipe ideas and cookbooks • How to manage social situations, eating out and travelling away from home, including travel abroad • Avoiding cross-contamination in the home and minimising the risk of accidental gluten intake when eating out • The role of national and local coeliac support groups Cumbria CCG currently has arrangement with community pharmacies and dispensing practices to supply patients with gluten free food direct without the need for a prescription. These arrangements are in line with NG20. Practices should not issue FP10 for gluten free food.
Liquid Proton Pump Inhibitor (PPI) Specials prescribing guidance	Guidance has been produced to aid prescribers to review the prescribing of liquid Proton Pump Inhibitor (PPI) specials (unlicensed preparations). Licensed alternatives should be used wherever possible. The guidelines can be found at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/
Community Pharmacy services	GPs are reminded that most Community Pharmacists offer a Medicines Use Review (MUR) service. An MUR consists of an accredited pharmacist undertaking a structured adherence-centred review with patients on multiple medicines, particularly those receiving medicines for long term conditions. National target groups have been agreed in order to guide the selection of patients to whom the service will be offered, including patients with respiratory and cardiovascular conditions. Pharmacists will check inhaler technique during an MUR and can assist your patients to achieve better outcomes by supporting them to optimise their use of medicines. Contact your local Pharmacist for more information. http://psnc.org.uk/services-commissioning/advanced-services/murs/
Luteinising hormone – releasing hormone (LHRH) agonists	Practices are reminded that the Lothian Joint Formulary first line LHRH agonist is Triptorelin (3 or 6 monthly injections). All new patients should be prescribed Triptorelin unless there are compelling reasons not to. This is the most cost effective treatment option. All LHRH agonists are AMBER (secondary care recommended) and RED (secondary care only) for unlicensed indications.

Warfarin Management Guidelines	Guidance has been updated to aid prescribers in the prescribing of Warfarin Staff undertaking dose adjustments for patients taking warfarin must now complete MHRA e learning module on anticoagulation. The guidelines can be found at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/
Anticoagulation Prescribing Guidance	The APC endorsed the Lancashire Medicines Management Group decision support tool " Anticoagulation Decision Support Tool: Stroke Prevention in adults with **Non-Valvular Atrial Fibrillation (NVAF)** (Version 2.0) " for use by clinicians in Cumbria to help prescribers pick the most suitable oral anticoagulant. The guidelines can be found at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/
Depression – treatment and management	NICE CG90 and CG91 were published in 2009 and state: • Use a stepped-care approach to depression, with antidepressants reserved for moderate-to-severe depression and for mild-to-moderate depression with inadequate response to initial interventions. • Dosulepin should not be prescribed • Antidepressants have largely equal efficacy and that choice should mainly depend on side-effect profile, people's preference and previous experience of treatments, propensity to cause discontinuation symptoms, safety in overdose, interactions and cost. • However, a generic SSRI is recommended as first-choice because of its favourable risk–benefit ratio. Neither escitalopram nor any of the available 'dual action' antidepressants, such as venlafaxine and duloxetine, were judged to have any clinically important advantages over other antidepressants. A review of antidepressant prescribing presented to Cumbria APC highlighted that Cumbria has consistently had the lowest proportion of QIPP first line antidepressants of all the NE and Cumbria CCGs over the last 3 years and that significant cost savings could be achieved if treatment was in line with NICE recommendations and LJF treatment choices. The APC made the following recommendations: 1. New patients should be prescribed first line SSRI antidepressants **fluoxetine or citalopram** 2. Should first line treatment not work then second line treatment would be **mirtazapine,** third line would be **venlaflaxine** 3. Patients taking venlafaxine MR doses of 150mg or less should be reviewed and switched to IR products wherever possible 4. **Dosulepin** has been allocated a **BLACK** rating in RAG list. All patients should be reviewed and switched to alternative, safer preparations wherever possible. Updated guidance to support prescribers is available at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/ 5. Patients taking **Doxepin** should be reviewed and switched to more appropriate antidepressants or antipruritics wherever possible

Lumigan eye drops	Allergan, the manufacturers of Lumigan (Bimatoprost®) eye drops, have discontinued the 0.03% drops. This has been replaced with a 0.01% preparation which is as effective so there should be no dosage adjustment when changing to the new product.
Antipsychotic prescribing	There are numerous antipsychotic drug (APD) preparations on the market and acquisition costs vary considerably. It is widely accepted that there is very little difference in efficacy between the APDs (except clozapine). However, there are notable differences in side-effect profiles and significant variation in cost. In Cumbria Quetiapine has featured in the top 50 most expensive drugs for the past several years. In 2013/14 Cumbria issued 11,599 prescriptions for quetiapine modified release (MR) at a cost of £565,369. Nearly three times as many (31,479) were issued for quetiapine immediate release (IR) costing less than a fifth of the MR version (£95,156). In 2014/15, £515,637 was still being spent on the MR version. A prescribing review was presented to the Cumbria APC highlighting the spend on MR products and the limited evidence for improved compliance with this formulation The APC made the following recommendations: 1. **Quetiapine IR is the preferred first line choice of APD** Exceptions: • Acutely unwell patients in whom the simplified titration and rapid dose escalation of the MR formulation (to achieve a therapeutic dose) can be used for the first three days, after which the IR preparation should be used. • Patients who develop intolerable side effects develop with the IR formulation, e.g. sedation and hypotension. In these cases the MR formulation may be considered. 2. **Patients currently prescribed quetiapine MR formulation should be switched to the quetiapine IR twice daily formulation** unless there are compelling clinical reasons not to do so, e.g. side effects and compliance where twice daily adherence to therapy may cause a problem. In discharge letters, psychiatrists should state the clinical justification of using an MR preparation if these are to be continued. 3. **Oro-dispersible and liquid formulations are not used for new patients** Oro-dispersible and liquid preparations should be reserved for patients with swallowing difficulties or compliance issues where these relate to preparation. 4. **Patients currently prescribed dispersible tablets should switched to standard tablets unless they have swallowing difficulties or compliance issues relating to preparation** 5. **Patients who need a soluble olanzapine formulation should be prescribed olanzapine orodispersible (Cost £3.83/28 tablets) NOT olanzapine oral lyophilisates sugar free (Cost £131.10/28 tablets)**

Recommendations on New Medicines

Drug	Indication	Recommendation
Tiotropium (Spiriva® Respimat®)	As add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids and long acting beta$_2$ agonists and who experienced one or more severe exacerbations in the previous year.	GREEN
Tiotropium / Olodaterol (Spiolto ® Respimat) ®	Maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.	GREY
Multivitamin (Vitamin A,D,E and K) (AquaDEKs®)	First choice multivitamin supplement in paediatric patients with cystic fibrosis.	GREEN
Triamcinolone Hexacetonide (Hexacetonide®)	For the treatment of juvenile idiopathic arthritis (JIA)	RED
Levonorgestrel (Levosert®)	Contraception, heavy menstrual bleeding	BLACK
Xailin Night eye ointment	Lubrication of dry eyes	GREEN
Calcium & Vitamin D supplement (theiCal-D3®)	For prevention and treatment of calcium and vitamin D deficiency. It will be used as an adjunct to specific osteoporosis treatments in patients at risk of calcium and vitamin D deficiency.	BLACK
Atomoxetine Oral solution 4mg/ml (Strattera®)	Treatment of attention-deficit/hyperactivity disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme.	AMBER
Toujeo Insulin Glargine 300units/ml	Treatment of Type 1 or Type 2 diabetes mellitus for patients needing high doses in small volumes	GREEN
Abasalgar Insulin Glargine biosimilar 100 units/ml	Treatment of Type 1 or Type 2 diabetes mellitus: First line option for use in adults who are eligible for treatment with insulin glargine in line with NICE guidance. Should be prescribed by brand name. New patients should be prescribed the most cost effective option available at that moment in time.	GREEN
E-cigarettes	Smoking cessation	BLACK

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News from the MHRA

Mycophenolate Mofetil, mycophenolic acid – new pregnancy prevention advice for women and men

(Drug safety update December 2015)

Mycophenolate mofetil and its active metabolite mycophenolic acid are associated with a high rate of serious birth defects and increased risk of spontaneous abortion.

Key updated safety advice for healthcare professionals:

- Mycophenolate mofetil or mycophenolic acid should not be used in pregnancy unless there is no suitable alternative treatment to prevent transplant rejection.
- Physicians should ensure that women and men taking mycophenolate mofetil and mycophenolic acid understand: the risk of harm to a baby; the need for effective contraception; the need to plan for pregnancy and change treatment as necessary; and the need to immediately consult a physician if there is a possibility of pregnancy.
- Mycophenolate mofetil or mycophenolic acid treatment should only be initiated in women of child bearing potential when there is a negative pregnancy test result to rule out unintended use in pregnancy.
- Mycophenolate mofetil or mycophenolic acid should only be given to women of childbearing potential who are using highly effective contraception.
- Women should use 2 forms of effective contraception during treatment and for 6 weeks after stopping treatment.
- Men (including those who have had a vasectomy) should use condoms during treatment and for at least 90 days after stopping treatment. This advice is a precautionary measure due to the genotoxicity of these products.
- Female partners of male patients treated with mycophenolate mofetil or mycophenolic acid should use highly effectice contraception during treatment and for 90 days after the last dose.

Mycophenolate mofetil (Cellcept), a prodrug of mycophenolic acid is an immunosuppressive agent used in combination with ciclosporin and corticosteroids for the prevention of acute transplant rejection in patients who have received kidney, heart, or liver transplants.

Bisphosphonates – very rare reports of osteonecrosis of the external auditory canal

(Drug safety update December 2015)

Bisphosphonates are used to treat osteoporosis, Paget's disease, and as part of some cancer regimens, particularly for metastatic bone cancer and multiple myeloma. Individual bisphosphonates have different indications (see individual Summaries of Product Characteristics). The following bisphosphonates are available in the UK:

- Alendronic acid
- Ibandronic acid
- Pamidronate disodium
- Risedronate sodium
- Sodium clodronate
- Zoledronic acid

Osteoporosis of the external auditory canal

Benign idiopathic osteonecrosis of the external auditory canal is a rare condition that can occur in the absence of antiresorptive therapy

	and is sometimes associated with local trauma. **Evidence for an association with bisphosphonate treatment** Evidence from the clinical literature and from cases reported to medicines regulators, including one report received via the UK Yellow Card scheme, supports a casual association between bisphosphonates and osteonecrosis of the external auditory canal. Product information is being updated to include advice for healthcare professionals and patients.
Nicorandil – now second line treatment for angina; risk of ulcer complications. **(Drug safety update January 2016)**	Note updated advice on use of nicorandil as second line treatment for stable angina; some ulcers may progress to complications unless treatment is stopped. Advice for healthcare professionals: • Use nicorandil for treatment of stable angina only in patients whose angina is inadequately controlled by first line anti-anginal therapies, or who have a contraindication or intolerance to first line anti-anginal therapies such as beta-blockers or calcium antagonists. • Nicorandil can cause serious skin, mucosal, and eye ulceration, including gastrointestinal ulcers which may progress to perforation, haemorrhage, fistula or abscess. • Stop nicorandil treatment if ulceration occurs – consider the need for alternative treatment or specialist advice if angina symptoms worsen. • Please continue to report suspected adverse drug reactions to nicorandil or any other medicines on a Yellow card.
Levonorgestrel – releasing intrauterine devices **(Drug safety update January 2016)**	Levonorgestrel – releasing intrauterine systems should always be prescribed by brand name because products have different indications, durations of use, and introducers. A levonorgestrel – releasing intrauterine system (IUS) has been available as the brand Mirena for a number of years. Recently, a second product called Levosert was licensed for use in the UK. Although Mirena and Levosert both contain 52mg levonorgestrel, they differ in two important ways: **Indications for use** • Mirena is licensed for 5 year' use and Levosert is licensed for 3 years' use in the indications of contraception or heavy menstrual bleeding. Clinical data or long term efficacy and safety of Mirena for contraception and heavy menstrual bleeding are available for 5 years of use, whereas 3 years of data are currently available for Levosert. • Mirena is also licensed for 4 years' use for endometrial protection as part of a hormone-replacement therapy regimen (Levosert is not licensed for this indication) **Introducer or insertion device** • Mirena and Levosert have different introducers, requiring different insertion techniques. Insertion (and removal) of any intra-uterine device (IUD) may be associated with pain, bleeding and (in some cases) perforation of the uterus. Therefore, IUDs should only be inserted by healthcare professionals who are experienced in insertion or who have had training in the relevant insertion techniques.

NICE guidance

These are brief summaries. The complete guidance should be consulted (www.nice.org.uk) NICE TAs which are only relevant in secondary care are not included here. RAG list status of any drug with a NICE TA can be checked on the NECS Medicines Optimisation website http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

NICE Clinical Guidelines are only included if there are recommendations on prescribing

	Drug	Condition	Summary
TA367	Vertioxetine	For treating major depressive episodes.	Vortioxetine (Brintellix) is recommended as a possible treatment for adults having a first or recurrent major depressive episode, if the current episode has not responded to 2 antidepressants. **GREEN**
TA369	Ciclosporin (Ikervis)	For treating dry eyes that have not improved despite treatment with artificial tears	Ciclosporin (Ikervis) is recommended as a possible treatment for people with dry eye disease that has not improved despite treatment with artificial tears. **AMBER**

	Condition	Recommendations
NG22	Older people with social care needs and multiple long term conditions	This guideline covers planning and delivering social care and support for older people who have multiple long-term conditions. It promotes an integrated and person-centred approach to delivering effective health and social care services. Recommendations include: Discuss managing medicines with each person and their carer as part of care planning Write any requirements about managing medicines into the care plan • the purpose of, and information on, medicines • the importance of dosage and timing and implications of non-adherence • details of who to contact in the case of any concerns
NG23	Menopause: Diagnosis and management	This guideline covers the diagnosis and management of menopause, including in women who have premature ovarian insufficiency. The guideline aims to improve the consistency of support and information provided to women in menopause.

		Recommendations cover 1.1 Individualised care 1.2 Diagnosis of perimenopause and menopause 1.3 Information and advice 1.4 Managing short-term menopausal symptoms 1.5 Long-term benefits and risks of hormone replacement therapy 1.6 Diagnosing and managing premature ovarian insufficiency
NG27	Transition between inpatient hospital settings and community or care home settings for adults with social care needs	This guideline covers the transition between inpatient hospital settings and community or care homes for adults with social care needs. It aims to improve people's experience of admission to, and discharge from, hospital by better coordination of health and social care services It includes the recommendation: 1.1.5 Give people information about their diagnoses and treatment and a complete list of their medicines when they transfer between hospital and home (including their care home). If appropriate, also give this to their family and carers
NG28	Type 2 Diabetes in adults: Management	This guideline covers the care and management of type 2 diabetes in adults (aged 18 and over). It focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications. This updated guideline includes new recommendations on: • individualised care • managing blood glucose levels: - HbA1c measurement and targets - self-monitoring of blood glucose - drug treatment • antiplatelet therapy

		• managing complications NICE have produced an treatment algorithm which has been populated with Cumbria formulary drug choices and can be found in the diabetes section http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/
NG31	Care of dying adults in the last days of life	This guideline covers the clinical care of adults (18 years and over) who are dying during the last 2 to 3 days of life. It aims to improve end of life care for people in their last days of life by communicating respectfully and involving them, and the people important to them, in decisions and by maintaining their comfort and dignity. The guideline covers how to manage common symptoms without causing unacceptable side effects and maintain hydration in the last days of life. This guideline includes recommendations on: • recognising when people are entering the last few days of life • communicating and shared decision-making • clinically assisted hydration • medicines for managing pain, breathlessness, nausea and vomiting, anxiety, delirium, agitation, and noisy respiratory secretions • anticipatory prescribing
NG33	Tuberculosis	This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults. It aims to improve ways of finding people who have TB in the community and recommends that everyone under 65 with latent TB should be treated. It describes how TB services should be organised, including the role of the TB control board. This guideline is applicable to secondary care service providing care to patients with TB

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