NHS
Cumbria
Clinical Commissioning Group

PRESCRIPTION PAD

The Newsletter of the Cumbria Area Prescribing Committee

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Clinical Policy and Formulary News

Mycophenlate mofetil

An updated version of the shared care protocol for Mycophenolate mofetil is now available. This covers prescribing of mycophenolate for off label indications. Any prescribing for licensed indications (Prophylaxis of rejection following organ transplant) should follow transplant protocols.

The SCP now includes the dermatological indications atopic eczema, bullous dermatoses, chronic actinic dermatitis, photoallergy, psoriasis and pyoderma gangrenosum.

There is strengthened advice on contraception necessary for both men and women taking mycophenolate mofetil as it is associated with a high rate of serious birth defects and spontaneous abortion.

Secondary care clinicians should initiate treatment and continue for at least 3 months and until the patients is stable.

All information on immunisations is now in a separate section.

Monitoring frequency is unchanged but there is a change to action to be taken if results are out of range, as , in some instances, it may be appropriate to continue treatment on specialist advice despite results being outside the reference range.

Available at http://medicines.necsu.nhs.uk/cumbria-shared-care-protocols/

Algorithm for blood glucose lowering therapy in adults with Type 2 Diabetes

This algorithm from NICE describes the treatment pathway for adults with Type 2 Diabetes in line with NG28. Local formulary choices are shown on the reverse and include the recommendation to prescribe insulin glargine as the biosimilar product, Abasaglar.

Available at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

Stroke Prevention in adults with NVAF - decision tool

Cumbria APC have adopted an updated version of the Lancashire Medicines Management Group decision support tool for Stoke Prevention in Adults with Non-Valvular Atrial Fibrilation (NVAF) (Version 2) which now includes Edoxaban in line with NICE TA355.

Available at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

Antibiotic management of recurrent urinary tract infections – updated guidance

These guidelines have been updated to reinforce safety information from MHRA particularly the need monitor patients prescribed Nitrofurantion and to be alert to the possibility that pulmonary conditions may be aggravated, especially in elderly patients.

Patients should be monitored closely for signs of hepatitis (particularly in long term use)
- **Close monitoring of the pulmonary conditions of patients receiving long-term therapy is warranted (especially in the elderly)**
- **Discontinue treatment with nitrofurantoin if otherwise unexplained pulmonary, hepatotoxic, haematological or neurological syndromes occur**
- Avoid in G6PD deficiency, upper UTI / pyelonephritis & near term
- Please advise women who are taking nitrofurantoin not to take alkalinising agents such as potassium citrate

Prescribers are reminded that Nitrofurantoin 100mg generic capsules are most cost-effective preparation, followed by 50mg generic capsules

The guidelines can be found at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

North East & Cumbria antimicrobial prescribing guideline for primary care

This guideline has been produced by the NECS Medicines Optimisation Team on behalf of CCGs in the North East and Cumbria. Treatment guidelines contained in this guide have been adapted from the Public Health England (formerly HPA) Management of Infection for Primary Care guidelines. This guideline is an update of the North East and Cumbria antibiotic prescribing guideline for primary care version 1.2, published in November 2014.
Changes from the previous guideline can be found on page 31-2, the main changes are summarised below:
Acute sore throat- PHE now suggest using the FeverPAIN scoring system as alternative to Centor criteria. Each clinical feature scores 1 point

- **Fever** in last 24 hours
- **P**urulence
- **A**ttend rapidly under 3 days
- **I**nflamed tonsils
- **N**o cough or coryza

Score 0-1 No antibiotic
Score 2-3 3 day back up prescription
Score>4 Prescribe antibiotic if severe or 48 hour back up prescription

Acute cough, bronchitis – Includes information on CRP testing in line with PHE and NICE guidance
Recurrent UTI – Comprehensive national UTI guidance is being developed by the British Association of Urological Surgeons, in the interim please continue to refer to the Cumbria guidelines "Antibiotic management of recurrent urinary tract infections" (See above)

UTI in men and non-pregnant women-Do not routinely dipstick to exclude UTI. In elderly patients >65 years, diagnosis should be based on full clinical assessment including vital signs. Dipstick tests are only indicated for women<65 years who have minimal signs and symptoms.

Threadworms- Manufacturer now recommends avoiding use in pregnancy. Preferred treatment is physical removal of eggs combined with hygiene methods.

Gonorrhoea- Antibiotic resistance is now very high, ideally patients with confirmed or suspected gonorrhoea should be referred to GUM clinic.

Pelvic inflammatory disease – Ciprofloxacin removed as treatment option in line with PHE guidance.

Cellulitis – Treatment classifications revised in line with PHE guidance. Treatment options added for patients on statins and facial cellulitis.

Fungal proximal finger or toenail infection –amorolfine removed as a treatment option, systemic therapy more effective.

Varicella zoster (chickenpox) and Herpes zoster (shingles) – first line treatment now acyclovir tablets (not dispersible) following price change.

Dental infections –emergency treatment. Metronidazole dose now 400mg TDS if spreading infection, in line with PHE guidance.

The guidelines can be found at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

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Recommendations on New Medicines

	Drug	Licensed indication	Recommendation
The following drugs have been recommended as suitable for use	Guanfacine 1mg, 2mg, 3mg and 4mg prolonged release tablets (Intuniv®)	Treatment of ADHD in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Treatment must be used as part of a comprehensive ADHD programme, typically including psychological, educational and social measures.	RED
	Insulin Detemir 100 units/ml solution for injection in cartridge (Penfill), pre-filled pen (FlexPen) and pre-filled pen (InnoLet) (Levemir®)	For treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.	GREEN
Lothian ammendments			
Respiratory update	**Adrenoceptor agonists** **(a) short–acting beta2–agonist bronchodilators** · **(b) long–acting beta2–agonist bronchodilators (LABA)** ·	Salbutamol Accuhaler has been deleted the Easyhaler is now the only dry powder device included. Formoterol turbohaler (Oxis) has been deleted, the Easyhaler is now the only dry powder device included. · Indacaterol has been removed from the choices box. It had been included as an option in COPD instead of a LAMA.	

	Antimuscarinic bronchodilators · The choices box has been amended extensively.	Tiotropium and glycopyrronium are no longer included as options for moderate-severe COPD. First choice LAMA is umeclidinium and second choice is aclidinium. · Tiotropium (Spiriva Respimat) is included for use in asthma. · Combination LAMA/LABA inhalers have now been included: Anoro Ellipta (umeclidinum with vilanterol) is first choice and Duaklir Genuair (aclidinium with formoterol) is second choice.
	Corticosteroids **(a) inhaled corticosteroids**	Fluticasone has been deleted as a second choice inhaled steroid. First choice is Clenil Modulite (MDI) or beclometasone Easyhaler (DPI) · Budesonide Easyhaler remains as second choice.
	c) combination corticosteroid products	The choices have been amended for asthma. Seretide and Symbicort have been deleted. · First choices for asthma and COPD are now the same – although the strengths of the inhalers are different. · Information has been added to the choices box detailing the doses to be prescribed at step 3 or 4 of asthma management and in COPD.

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News from the MHRA

Valproate and risk of abnormal pregnancy outcomes – new communication materials

(Drug safety update February 2016)

In January 2015 the MHRA informed clinicians that children exposed to valproate in utero are at high risk of development disorders and congenital malformations. To further improve awareness of the risks of valproate in pregnancy MHRA have requested that clnicians use the new communication materials below to support discussion of these risks with women of childbearing potential and girls who take valproate. Your practice should have received hard copies.

Resources to use:

1. Booklet for healthcare professionals
2. Consultation checklist
3. Guide to give to patients
4. Card to give to patients.

Summary of risks and precautions

Children exposed in utero to valproate are at a high risk of serious developmental disorders (in up to 30-40% of cases) and congenital malformations (in approximately 10% of cases)1-9

• Valproate should not be prescribed to female children, female adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated.

• Valproate treatment must be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder.

• Carefully balance the benefits of valproate treatment against the risks when prescribing valproate for the first time, at routine treatment reviews, when a female child reaches puberty and when a woman plans a pregnancy or becomes pregnant.

• Clinicians must ensure that all female patients are informed of and understand:

o the risks associated with valproate during pregnancy;

o the need to use effective contraception;

o the need for regular review of treatment;

o the need to rapidly consult if she is planning a pregnancy or becomes pregnant

For pharmacists

• Whenever you dispense a medicine related to valproate for a woman of childbearing potential or girl, give her a patient card, unless she confirms that she already has one.

• Encourage her to read the card (example in figures below) and enter her name and date to reinforce her own accountability to consider the information it contains.

• If you manage dispensing services in your organisation, ensure that processes are in place to allow these requirements to be met.

• Please continue to report any suspected side effects to valproate or any other medicine on a Yellow Card (see also guidance on

reporting side effects experienced by the woman or child to medicines taken during pregnancy).

For general practitioners:

• Valproate treatment must be started and supervised by a specialist experienced in managing epilepsy or bipolar disorder.

• Consider the need to arrange treatment reviews with the relevant specialist for women of childbearing potential and girls who are currently taking valproate.

• If a woman who is taking valproate tells you she is pregnant or would like to have a baby, refer her to the specialist responsible for her care.

• Please continue to report any suspected side effects to valproate or any other medicine on a Yellow Card (see also guidance on reporting side effects experienced by the woman or child to medicines taken during pregnancy).

Off-label use: risks and advice still apply

Valproate is not licensed for treatment of conditions other than epilepsy or bipolar disorder in the UK. However, we are aware that these medicines are sometimes used 'off-label' (eg for migraine or chronic pain). If you are considering initiating or continuing such treatment, the same risks and advice in this article apply.

Spironolactone and renin-angiotensin system drugs in heart failure: risk of potentially fatal hyperkalaemia

(Drug safety update February 2016)

Monitoring of blood electrolytes is essential in patients co-prescribed a potassium sparing diuretic and an angiotensin converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB) for heart failure.

The MRHA have seen an increase in the number of suspected ADRs reported for this combination, some of which were fatal.

Reminder for healthcare professionals:

1. Concomitant use of spironolactone with ACEi or ARB is not routinely recommended because of the risks of severe hyperkalaemia particularly in patients with marked renal impairment.
2. Use the lowest effective doses of spironolactone and ACEi or ARB if coadministration is considered essential.
3. Regularly monitor serum potassium levels and renal function.
4. Interrupt or discontinue treatment in the event of hyperkalaemia.
5. Suspected adverse reactions should be reported to the MHRA on a yellow card.

NICE guidance

These are brief summaries. The complete guidance should be consulted (www.nice.org.uk)

	Drug	Condition	Summary
TA384	Nivolumab	Recommended as an option for monotherapy for advanced melanoma	Nivolumab as monotherapy is recommended, within its marketing authorisation, as an option for treating advanced (unresectable or metastatic) melanoma in adults. RED
TA385	Ezetimibe	For treating primary heterozygous-familial and non-familial hypercholesterolaemia	This guidance should be used with NICE's guidelines on cardiovascular disease: risk assessment and reduction, including lipid modification and familial hypercholesterolaemia: identification and management. **No significant changes to recommendation from previous guidance.**
TA386	Ruxolitinib (replaces TA289)	For treating disease related splenomegaly or symptoms in adults with myelofibrosis	These drugs are for adults with disease-related splenomegaly or symptoms caused by primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, only if they have intermediate-2 or high-risk disease.RED

	Condition	Recommendations
NG34	Sunlight Exposure: Risks and benefits	This guideline covers how to communicate the risks and benefits of natural sunlight exposure (specifically, the ultraviolet rays UVA and UVB) to help people understand why they may need to

		modify their behaviour to reduce their risk of skin cancer and vitamin D deficiency.
NG35	Myeloma: Diagnosis and management	This guideline covers the diagnosing and managing of myeloma (including smouldering myeloma and primary plasma cell leukaemia) in people aged 16 and over. It aims to improve care for people with myeloma by promoting the most effective tests and treatments for myeloma and its complications.
NG36	Cancer of the upper aerodigestive tract: assessment and management in people aged 16 or over	This guideline covers assessing and managing cancers of the upper aerodigestive tract in young people (aged 16 and over) and adults. It aims to reduce variation in practice and improve survival.
NG37	Fractures (complex) Assessment & management	This guideline covers assessing and managing pelvic fractures, open fractures and severe ankle fractures (known as pilon fractures and intra-articular distal tibia fractures) in pre-hospital settings (including ambulance services), emergency departments and major trauma centres. It aims to reduce deaths and long-term health problems by improving the quality of emergency and urgent care.
NG38	Fractures (complex) Assessment & management	This guideline covers assessing and managing non-complex fractures that can be treated in the emergency department ororthopaedic clinic. It aims to improve practice so that people with fractures receive the care that they need Without unnecessary tests and treatments.

NG39	Major trauma: Assessment & initial management	This guideline covers the rapid identification and early management of major trauma in pre-hospital and hospital settings, including ambulance services, emergency departments, major trauma centres and trauma units. It aims to reduce deaths and disabilities in people with serious injuries by improving the quality of their immediate care. It does not cover care for people with burns.
NG40	Major trauma; Service delivery	This guideline covers the organisation and provision of major trauma services in pre-hospital and hospital settings, including ambulance services, emergency departments, major trauma centres and trauma units. It aims to reduce deaths and disabilities in people with serious injuries by providing a systematic approach to the delivery of major trauma care. It does not cover services for people with burns.
NG41	Spinal injury: assessment & initial management	This guideline covers the assessment and early management of spinal column and spinal cord injury in pre-hospital settings (including ambulance services), emergency departments and major trauma centres. It covers traumatic injuries to the spine but does not cover spinal injury caused by a disease. It aims to reduce death and disability by improving the quality of emergency and urgent care.

NG42	Motor Neurone disease: assessment & management	This guideline covers assessing and managing motor neurone disease (MND). It aims to improve care from the time of diagnosis, and covers information and support, organisation of care, managing symptoms and preparing for end of life care. **GPs who are caring for patients with motor neurone disease should familiarise themselves with the contents of this guideline which includes recommendations on pharmacological treatments for muscle problems, saliva problems and respiratory function and symptoms.**
NG43	Transition from children's to adult's services for young people using health or social care services	This guideline covers the period before, during and after a young person moves from children's to adults' services. It aims to help young people and their carers have a better experience of transition by improving the way it's planned and carried out. It covers both health and social care
NG44	Community engagement: Improving health & wellbeing & reducing health inequalities	This guideline covers community engagement approaches to reduce health inequalities, ensure health and wellbeing initiatives are effective and help local authorities and health bodies meet their statutory obligations.

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