NHS Cumbria Clinical Commissioning Group

PRESCRIPTION PAD

The Newsletter of the Cumbria Area Prescribing Committee

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Clinical Policy and Formulary News

Nutilis Clear®

The APC has agreed that Nutilis Clear® should be the feed thickener of choice in North and West Cumbria, replacing Thick and Easy®. It has some advantages over Thick and Easy®, as it does not lose its effect in the presence of saliva amylase, is less likely to layer out and is generally more palatable. There may still be occasions where the Speech & Language Therapy Team recommends an alternative product in individual patients.

Although there are a number of similar thickening products available, they have to be made up slightly differently. It is important that the patient/carer is advised to read the instructions for reconstitution of the product.

There is no need for existing patients to change their product, although prescribers may choose to offer Nutilis Clear® to improve palatability, or to avoid confusion in residential institutions where the use of a number of different thickening products may cause confusion.

In the South of Cumbria, practices should continue to follow the advice of local Speech and Language Therapy Teams.

Gaviscon® vs. Peptac®

Peptac® is the first-choice alginate-containing agent in the Lothian formulary. There are modest savings to be made by prescribing Peptac® rather than Gaviscon®, which is the most widely agent used at present.

	Gaviscon® (original)	Gaviscon Advance®	Peptac®
Licensed indication	Gastric reflux, heartburn, flatulence associated with gastric reflux, heartburn of pregnancy, all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.	Treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals, or during pregnancy, or in patients with symptoms related to reflux oesophagitis	Indicated in heartburn, including heartburn of pregnancy, dyspepsia associated with gastric reflux, hiatus hernia, reflux oesophagitis, regurgitation and all cases of epigastric and retrosternal distress where the underlying cause is gastric reflux.
Ingredients (per 5ml)	Sodium alginate 250mg Sodium bicarbonate 133.5mg Calcium carbonate 80mg	Sodium alginate 500mg Potassium hydrogen carbonate 20mg	Sodium bicarbonate 133.5mg Sodium alginate 250mg Calcium carbonate 80mg
Dose	10-20ml after meals and at bedtime.	5-10 ml after meals and at bedtime.	Adults and children over 12 years: 10-20ml after meals and at bedtime.
Sodium content (for maximum dose)	20ml dose - 282mg (12.4mmol).	10ml dose - 106mg (4.6mmol).	20ml dose = about 12mmol.
Cost per bottle (eMIMS), October 2014)	300ml, £4.20 600ml, £6.89	250ml, £2.56 500ml, £5.12	500ml, £1.95
Cost for 28 days (based on maximum dose, taken four times a day)	£25.72	£11.46	£8.74

Incontinence pathway

A detailing aid, outlining the recommended treatment of overactive bladder in women has been approved by APC. A copy is available here. It includes advice on both non-drug and drug treatments.

Antibiotic guidelines	The North of England Primary Care Antibiotic guidelines are now available, either in a complete and an abbreviated form. These have been agreed by all microbiologists in the North of England. In addition, there will be an app that contains the North of England Antimicrobial guidelines. The app is called Microguide and is available for both iPhone and Android operating systems (sorry, mobile phone not supplied!). The guidelines are not available on the app just yet, but will be in the new year.
Pneumococcal revaccination	Pneumococcal polysaccharide vaccine (PPV23) is normally given as a single dose to patients at increased risk of pneumococcal disease. These include patients with asplenia or dysfunction of the spleen, chronic respiratory, heart, kidney or liver disease, diabetes or immunosuppression. Pneumococcal revaccination is licensed 'for persons at increased risk of serious pneumococcal infection who were given pneumococcal vaccine more than five years earlier or for those known to have a rapid decline in pneumococcal antibody levels'. Antibody levels are likely to decline rapidly in individuals with no spleen, splenic dysfunction or chronic renal disease and therefore re-immunisation with PPV23 is recommended every five years in these groups. Revaccination is normally well tolerated. Testing of antibody levels prior to vaccination is not required. Although there is evidence of a decline in protection with time, there are no studies showing additional protection from boosting individuals with other indications, including age, and therefore routine revaccination is not currently recommended.
Changes to the Lothian Joint Formulary	**Locorten Vioform® ear drops** are no longer available as a branded product. They should be prescribed as flumetasone 0.02% / clioquinol 1% ear drops. The choices box has been amended accordingly. **Progestogen–only contraceptives -** This section has been updated to include the progestogen-only contraceptives by generic name. In line with the policy on branded generics, these should be prescribed generically, not by brand name.

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Recommendations on New Medicines

	Drug	Licensed indication	Recommendation
The following drugs have been recommended as suitable for use:	Fluticasone + vilanterol 92/22 inhaler (Relvar Ellipta®)	Symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in 1 second (FEV_1) <70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	It is recommend for use in patients with severe COPD but only if FEV_1 <50% predicted normal). **GREEN** If FEV_1 is greater than 50%, but less than 70%, it is **BLACK**
	Beclometasone + formoterol inhaler (Fostair®)	Symptomatic treatment of patients with severe COPD (FEV_1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.	Accepted for use. **GREEN**
	Solifenacin + tamsulosin (Vesomni®)	Treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy.	In patients for whom concomitant use of solifenacin succinate and tamsulosin hydrochloride is appropriate, Vesomni® allows administration of a single tablet at a lower cost compared to the individual components administered separately. **GREEN**
The following drug was <u>not approved</u> by SMC and LJF, on the basis that a cost-effectiveness case was not submitted by the manufacturer:	Colestilian (BindRen®)	Treatment of hyperphosphataemia in adult patients with chronic kidney disease stage 5 receiving haemodialysis or peritoneal dialysis.	The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. **BLACK**
	Olodaterol inhaler (Striverdi Respimat®)	Maintenance bronchodilator treatment in patients with COPD.	

	Drug	Licensed indication	Recommendation
The following drug was <u>not approved</u> by SMC and LJF, on the basis that a cost-effectiveness case was not submitted by the manufacturer:	Racecadotril (Hidrasec Infant®, Hidrasec Children®)	Complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children.	The submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC. **BLACK**
	Umeclidinium + vilanterol inhaler (Anoro®)	As a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.	
	Tetracaine + lidocaine cream (Pliaglis®)	Local dermal anaesthesia on intact skin prior to dermatological procedures in adults.	

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News from the MHRA

Denosumab	Denosumab is associated with a risk of osteonecrosis of the jaw (ONJ) and with a risk of hypocalcaemia. Before starting denosumab treatment, a dental examination and appropriate preventive dentistry are now recommended to reduce the risk of osteonecrosis of the jaw. This applies to all patients considered for denosumab 120mg for cancer and to patients with ONJ risk factors considered for denosumab 60mg for osteoporosis (see below). Tell patients to maintain good oral hygiene and report any oral symptoms. The risk of hypocalcaemia increases with the degree of renal impairment. Monitor calcium levels depending on the indication as described below and tell patients to report symptoms of hypocalcaemia. These include muscle spasms, twitches, or cramps; numbness or tingling in the fingers, toes, or around the mouth. In addition, calcium levels should be checked: • before each dose • within two weeks after the initial dose in patients with risk factors for hypocalcaemia (e.g., severe renal impairment, creatinine clearance <30 ml/min) • if suspected symptoms of hypocalcaemia occur.
Nitrofurantoin	Nitrofurantoin is now contra-indicated in patients with an estimated glomerular filtration rate (eGFR) of less than 45 ml/min. However, a short course (3 to 7 days) may be used with caution in certain patients with an eGFR of 30 to 44 ml/min. Only prescribe to such patients to treat lower UTIs with suspected or proven multidrug resistant pathogens when the benefits of nitrofurantoin are considered to outweigh the risks of side effects. This contra-indication allows nitrofurantoin to be used in patients for whom it was previously not recommended (see below) • Nitrofurantoin is contra-indicated in patients with an estimated glomerular filtration rate (eGFR) of less than 45 ml/min. • A short course (3 to 7 days) may be used with caution in certain patients with an eGFR of 30 to 44 ml/min. Only prescribe to such patients to treat lower urinary tract infection with suspected or proven multidrug resistant pathogens when the benefits of nitrofurantoin are considered to outweigh the risks of side effects. • Nitrofurantoin should not be used to treat sepsis syndrome secondary to urinary tract infection or suspected upper UTIs... • Consider checking renal function when choosing to treat with nitrofurantoin, especially in the elderly. • Closely monitor for signs of pulmonary, hepatic, neurological, haematological, and gastro-intestinal side effects during treatment, as advised in the summary of product characteristics.

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NICE guidance

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

	Drug	Condition	Summary
TA320	Dimethyl fumarate	Multiple sclerosis, relapsing-remitting	Recommended as a possible treatment for people with active relapsing-remitting multiple sclerosis that isn't highly active or rapidly evolving severe relapsing-remitting multiple sclerosis. **RED**
TA322	Lenalidomide	Transfusion-dependent anaemia, caused by low- or intermediate-1 risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality	Recommended as an option. **RED**

CG182	**Chronic kidney disease**	Guidance covers the identification and classification of chronic kidney disease (CKD) in adults. **Specific medicines related recommendations include:** Blood pressure - keep the systolic blood pressure below 140mmHg (target range 120–139mmHg) and the diastolic blood pressure below 90mmHg in people with CKD and diabetes, and also in people with an Albumin Creatinine Ratio (ACR) of 70mg/mmol or more, aim to keep the systolic blood pressure below 130mmHg (target range 120–129mmHg) and the diastolic blood pressure below 80mmHg. **Choice of antihypertensive agent** - Offer a low-cost ACE inhibitor (LJF choices, ramipril or lisinopril), an angiotensin-II receptor antagonist (candesartan or losartan) or aliskiren to people with CKD and: • diabetes and an ACR of 3mg/mmol or more (ACR category A2 or A3) • hypertension and an ACR of 30mg/mmol or more (ACR category A3) • an ACR of 70mg/mmol or more (irrespective of hypertension or cardiovascular disease) Do **not** offer a combination of renin–angiotensin system antagonists to people with CKD. In people with CKD, measure serum potassium concentrations and estimate the GFR before starting renin–angiotensin system antagonists. Repeat these measurements between 1 and 2 weeks after starting renin–angiotensin system antagonists and after each dose increase.

Do not routinely offer a renin–angiotensin system antagonist to people with CKD if their pre-treatment serum **potassium** concentration **is greater than 5.0mmol/litre**. When hyperkalaemia precludes use of renin–angiotensin system antagonists, assessment, investigation and treatment of other factors known to promote hyperkalaemia should be undertaken and the serum potassium concentration rechecked. Concurrent prescription of drugs known to promote hyperkalaemia is not a contra-indication to the use of renin–angiotensin system antagonists, but be aware that more frequent monitoring of serum potassium concentration may be required.

Stop renin–angiotensin system antagonists if the serum potassium concentration **increases to 6.0mmol/litre** or more and other drugs known to promote hyperkalaemia have been discontinued.

Following the introduction or dose increase of renin–angiotensin system antagonists, do not modify the dose if either the GFR decrease from pre-treatment baseline is less than 25% or the serum creatinine increase from baseline is less than 30%.

If there is a decrease in eGFR or increase in serum creatinine after starting or increasing the dose of renin–angiotensin system antagonists, but it is less than 25% (eGFR) or 30% (serum creatinine) of baseline, repeat the test in 1–2 weeks. Do not modify the renin–angiotensin system antagonist dose if the change in eGFR is less than 25% or the change in serum creatinine is less than 30%.

If the eGFR change is 25% or more, or the change in serum creatinine is 30% or more, investigate other causes of a deterioration in renal function, such as volume depletion or concurrent medication (for example, NSAIDs). If no other cause for the deterioration in renal function is found, stop the renin–angiotensin system antagonist or reduce the dose to a previously tolerated lower dose, and add an alternative antihypertensive medication if required.

Offer atorvastatin 20mg for the primary or secondary prevention of CVD to people with CKD. Increase the dose if a greater than 40% reduction in non-HDL cholesterol is not achieved and eGFR is 30ml/min/1.73m^2 or more. Agree the use of higher doses with a renal specialist if eGFR is less than 30ml/min/1.73m^2

Offer antiplatelet drugs to people with CKD for the secondary prevention of cardiovascular disease, but be aware of the increased risk of bleeding. Consider apixaban in preference to warfarin in people with a confirmed eGFR of 30–50ml/min/1.73m^2 and non-valvular atrial fibrillation who have 1 or more of the following risk factors:

- prior stroke or transient ischaemic attack
- age 75 years or older
- hypertension
- diabetes mellitus
- symptomatic heart failure.

		The NICE Bites is available here.
CG183	**Drug allergy**	Emphasis on the diagnosis of anaphylaxis and other manifestations of drug allergy. If drug allergy is suspected: • consider stopping the drug suspected to have caused the allergic reaction and advising the person to avoid that drug in future • treat the symptoms of the acute reaction if needed; send people with severe reactions to hospital • document details of the suspected drug allergy in the person's medical records Refer people to a specialist drug allergy service if they have had: • a suspected anaphylactic reaction, or • a severe non-immediate cutaneous reaction (for example, drug reaction with eosinophilia and systemic symptoms [DRESS], Stevens–Johnson Syndrome, toxic epidermal necrolysis). There is specific advice on dealing with allergies due to NSAIDs, beta-lactam antibiotics, local and general anaesthetics.
CG184	**Dyspepsia and gastro-oesophageal reflux disease**	This guidance covers the management of dyspepsia and GORD in adults over 18 years. The main change in the treatment is the recommendation of higher doses of PPIs for the treatment of severe oesophagitis. These are omeprazole 40mg once or twice a day and lansoprazole 30mg once or twice a day. It again recommends that after treatment with standard doses of a PPI, consideration should be given to stepping down the dose and considering therapy on an 'as required' rather than regular basis. The local flowcharts may be accessed here and the NICE Bites resume here.
CG185	**Bipolar disorder**	Much of the guidance relates to recommendations of services that should be available to patients with bipolar disorder. It recommends that as far as initial treatment is concerned, lithium should not be commenced in primary care for people who have not taken lithium before, except under shared-care arrangements. Valproate should not be started in primary care to treat bipolar disorder. Ensure that the physical health check for people with bipolar disorder, performed at least annually, includes: • weight or BMI, diet, nutritional status and level of physical activity • cardiovascular status, including pulse and blood pressure

		• metabolic status, including fasting blood glucose, glycosylated haemoglobin (HbA_{1c}) and blood lipid profile • liver function • renal and thyroid function, and calcium levels, for people taking long-term lithium. The guidance also makes recommendation for treatment in secondary care, suggesting the possible use of antipsychotics if appropriate.
CG30	**Long-acting reversible contraception (update)**	Long-acting reversible contraception (LARC's) methods are more cost-effective than the combined oral contraceptive pill, even at 1one year of use. NICE Bites provides a summary of the benefits and drawbacks of the different types of LARC available.

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