NHS Cumbria Clinical Commissioning Group

PRESCRIPTION PAD

The Newsletter of the Cumbria Area Prescribing Committee

April 2014 No. 29

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Clinical policy and Formulary news	Recommendations on new medicines	NICE Guidance
Fosfomycin	Atomoxetine capsules (Strattera®)	TA303 – Teriflunomide, multiple sclerosis (remitting)
Mesalazine	Imiquimod cream (Zyclara®)	
Prescribing restrictions for strontium	Fentanyl citrate buccal film (Breakyl®)	
Ticagrelor	Azelastine & fluticasone nasal spray (Dymista®)	CG174 – Intravenous fluid therapy in hospital
Shortage of valsartan	Saxagliptin tablets (Onglyza®)	CG175 – prostate cancer
		CG176 – Head injury

Clinical Policy and Formulary News

Fosfomycin	Fosfomycin was mentioned in the last Prescription Pad, as an option for the treatment of symptomatic lower UTI in adult men and non-pregnant women where multi-resistant coliforms are identified (e.g., ESBL-positive *E.coli*) from urine culture. It was mentioned that It should be used only on the recommendation of a consultant microbiologist, but we forgot to say that, by definition, it is classified as **AMBER**.
Mesalazine	Mesalazine should be prescribed by its trade name to ensure that the patients receive a consistent formulation. Differences have been seen in the past in bioavailability of the different brands. About a quarter of oral mesalazine preparations prescribed in Cumbria are prescribed generically, It is recommended that these be changed to a brand and that brand should be Octasa®. Octasa® is actually less expensive than generic mesalazine.

Prescribing restrictions for strontium	Following a European review, the Medicines and Healthcare products Regulatory Agency (MHRA) has updated advice to healthcare professionals that strontium ranelate (Protelos®), used to treat severe osteoporosis in post-menopausal women and men with a high risk of fracture, should only be prescribed to patients who do not have a history of heart problems and if the patient is unable to take other medicines for this condition.
	
	The MHRA have now changed their advice on the indications and monitoring required:
	
	• Strontium ranelate is now restricted to the treatment of severe osteoporosis in postmenopausal women and adult men at high risk of fracture who cannot use other osteoporosis treatments due to, for example, contra-indications or intolerance
	• Treatment should only be started by a physician with experience in the treatment of osteoporosis
	• The risk of developing cardiovascular disease should be assessed before starting treatment. Treatment should not be started in people who have or have had:
	  ○ ischaemic heart disease
	  ○ peripheral arterial disease
	  ○ cerebrovascular disease
	  ○ uncontrolled hypertension
	• Cardiovascular risk should be monitored every 6–12 months
	• Treatment should be stopped if the individual develops ischaemic heart disease, peripheral arterial disease, or cerebrovascular disease, or if hypertension is uncontrolled

Ticagrelor	Prescribers are reminded that ticagrelor is only licensed for use up to 12 months. After this, it should be discontinued as per the NICE guidance on ticagrelor and the clinical guideline on secondary prevention after myocardial infarction.

Shortage of valsartan

There is currently a shortage of Valsartan (Diovan®) - generic and brand, currently in 80mg & 160mg strengths. Resolution is not expected until at least April and may not be until July. 40mg tablets are still available at the moment, but there may be an increased demand on this strength, so supplies are likely to dry up for this as well.

Alternative angiotensin-II receptor antagonists (A-IIRA's) are available, but the indications for these vary. The LJF choices are as follows:

	Hypertension	**Heart failure**	**Renal disease including diabetic nephropathy**	**Post-MI prophylaxis**	**CV risk reduction**
Candesartan	✓	✓			
Irbesartan	✓		✓		
Losartan	✓	✓	✓		✓
Valsartan	✓	✓		✓	

Information on dosing equivalents of AIIRA's is not available. If changing a patient from one A-IIRA to another, where the dose falls within the dosing range should be taken into account (i.e., low, maintenance low or maintenance high, or maximum dose) and the equivalent for losartan used. Blood pressure must be closely monitored. Even if rough estimates of equivalent dosing are made, it is prudent to compare where in the dosing range the current AIIRA is and start at a lower or similar dose for the new product, e.g., bottom, middle or top of the dosing range. The dose of the drug is usually increased every 2-4 weeks, but can be increased weekly, depending on the severity of the hypertension and how well the patient tolerates the dose increase.

For elderly patients or patients with renal impairment it is advisable to start on a lower dose than direct equivalent and titrate as required.

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Recommendations on New Medicines

The following drugs have been recommended as suitable for use:	Atomoxetine capsules Strattera®	Treatment of ADHD in **adults** as part of a comprehensive treatment programme. The presence of symptoms that were pre-existing in childhood should be confirmed.	Added to the formulary **AMBER**
The following drugs were <u>not approved</u> by SMC and LJF, on the basis that a cost-effectiveness case was not submitted by the manufacturer:	Imiquimod cream Zyclara®	Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contra-indicated or less appropriate.	Not recommended **BLACK**
	Fentanyl citrate buccal film Breakyl®	Treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.	Not recommended **BLACK**
The following drugs were <u>not approved</u> by SMC and LJF, on the basis that a cost-effectiveness case was not proven by the manufacturer:	Azelastine & fluticasone nasal spray Dymista®	Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.	Not recommended **BLACK**
The following drugs were <u>not approved</u> by SMC and LJF, on the basis that other agents were preferred by the LJF:	Saxagliptin tablets Onglyza®	In adult patients aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control as triple oral therapy in combination with metformin plus a sulphonylurea when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.	Not recommended **BLACK** Sitagliptin is the preferred agent.

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NICE guidance

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

	Drug	Condition	Resume
TA303	**Teriflunomide**	Multiple sclerosis (remitting)	Recommended for treating adults with active relapsing–remitting multiple sclerosis (normally defined as 2 clinically significant relapses in the previous 2 years), only if they do not have highly active or rapidly evolving severe relapsing–remitting multiple sclerosis. RED
CG174	**Intravenous fluid therapy in hospital**		This guideline outlines: • physiological principles that underpin fluid prescribing • pathophysiological changes that affect fluid balance in disease states • indications for IV fluid therapy • reasons for the choice of the various fluids available and • principles of assessing fluid balance.
CG175	**Prostate cancer**		Offer men with intermediate and high risk localised prostate cancer a combination of radical radiotherapy and androgen deprivation therapy rather than either therapy alone. (New recommendation.) Offer men with intermediate and high risk localised prostate cancer six months of androgen deprivation therapy before, during, or after radical external beam radiotherapy and consider extending this for up to three years for men with high risk disease. (New recommendation.) Consider intermittent therapy for men having long term androgen deprivation therapy (but not in the adjuvant setting after radical treatment with radiotherapy or surgery), and include discussion with the patient, and his family or carers if he wishes, about: • The rationale for intermittent androgen deprivation therapy • The limited evidence for reduction in side effects from intermittent therapy • The effect of intermittent therapy on progression of prostate cancer.
CG176	**Head injury**		Guideline deals with the initial assessment and management of patients. It makes no recommendation on the use of any drugs.

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