NHS Cumbria Clinical Commissioning Group

PRESCRIPTION PAD

The Newsletter of the Cumbria Area Prescribing Committee

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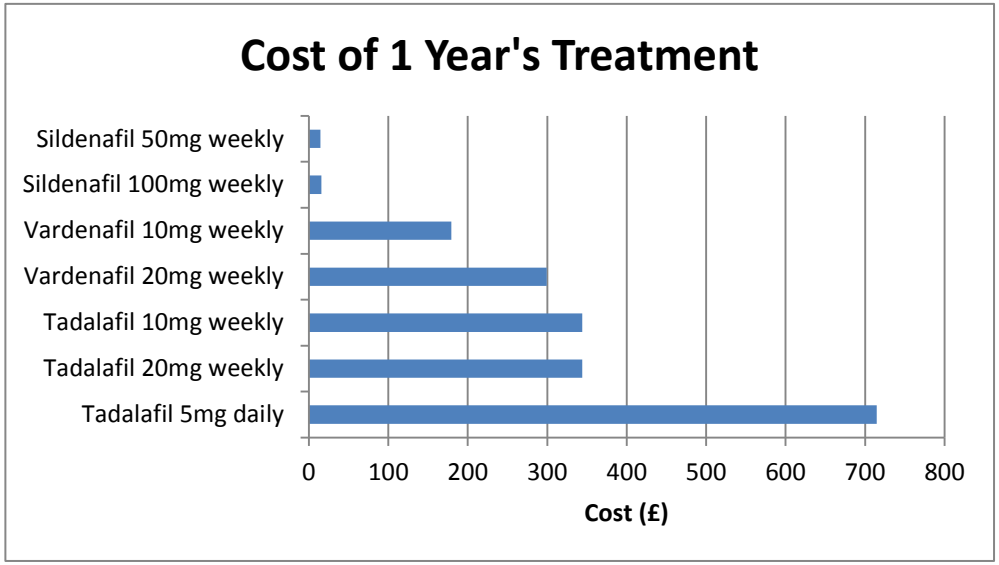
Clinical Policy and Formulary News

Drugs for erectile dysfunction

The patent for sildenafil expired in October 2013, leading to a significant reduction in cost (at least 15-fold reduction).

Prescribers are reminded that sildenafil is the first-choice drug for the treatment of erectile dysfunction. Tadalafil may be a suitable alternative for patients who develop visual disturbances with sildenafil or for whom a longer duration of action is required.

The Department of Health has recently closed a consultation on relaxing the directions on the number of treatments that can be prescribed and which patients are eligible for treatment under the NHS. It is likely that these restrictions will be relaxed, but until such time that the new regulations are published, the existing regulations should be followed.



The price of the weekly treatment is based on the current DH advice (HSC1999/148)

Adrenaline pens

People who have been prescribed an adrenaline auto-injector because of the risk of anaphylaxis should **carry** two with them at all times for emergency, on-the-spot use. After every use of an adrenaline auto-injector, an **ambulance should be called** (even if symptoms are improving), the individual should lie down with their legs raised and, if at all possible, should not be left alone.

Jext®, which is the preferred adrenaline autoinjector is now available again asfter the recent supply problems.

High-strength fluoride toothpastes

Duraphat® is a high-strength fluoride toothpaste containing either 2800ppmF (parts per million Fluoride) or 5000ppmF, as opposed to normal commercial toothpaste, which contains about 1400ppmF.

The 2800ppmF preparation is indicated where there is a high caries risk patients aged ten years and over, those with caries present, orthodontic appliances, a highly cariogenic diet or medication. The 5,000ppmF toothpaste is indicated for patients aged 16 years and over with high caries risk, present or potential for root caries, dry mouth, orthodontic appliances, overdentures, and those with highly cariogenic diet or medication.

These are started by dentists, but there are an increasing number of prescriptions being written by GPs after requests from dentists or patients. These preparations need to be used under close supervision, due to the risk of fluorosis.

Fluorosis is an uncommon condition, caused by the ingestion of excessive quantities of fluoride. In the UK, there is no upper safety limit set for the daily amount of fluoride that can be ingested, but in the US, it is set at 10mg daily.

A 70 kilogram adult, who does not expectorate after brushing, could ingest a total of 10 mg fluoride by swallowing 2.0 ml of Duraphat® 5000 toothpaste, assuming a fluoride-free water supply. Alternatively 10 mg of fluoride is also ingested with 1.7 ml Duraphat® 5000 toothpaste plus 1.5 litres water containing 1 ppmF. Caution is required if high-strength fluoride toothpastes are used in people who may swallow rather than expectorate after toothbrushing.

Mild dental fluorosis can be seen as very fine pearly white lines or flecking on the surface of the teeth. It can often only be diagnosed by a dental expert because other conditions may give a similar appearance. Severe fluorosis can cause the tooth's enamel to become pitted or discoloured.

As dentists are best placed to assess both the benefits and risks of treatment, they should prescribe high-strength toothpastes. They should not be prescribed by GP's.

Vitamin B Co Strong for alcohol detoxification

One of the main risks of alcohol abuse and detoxification is the risk of precipitating Wernicke's encephalopathy. To reduce the risk of this, the NICE guideline recommends the use of intravenous thiamine, followed by oral thiamine.

Confusion arises due to the in-patient use of Pabrinex®, which contains other vitamins, apart from thiamine. This is used as it is the only licensed injection that contains thiamine. NICE does not make recommendations about the administration of vitamins, apart from thiamine. The dose and duration of thiamine therapy are not specified in the NICE guideline, but are likely to be in the range of 200 to 300mg a day. The benefit of giving vitamin B Co Strong tablets, which contain 5mg is unlikely to be of any additional benefit.

It is therefore recommended that vitamin B Co Strong tablets should not be used as part of the alcohol detoxification regime.

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Recommendations on New Medicines

The following drugs have been recommended as suitable for use:	Aripiprazole tablets, 5, 10, 15, 30mg tablets, 15mg orodispersible tablets, 1mg/ml oral solution (Abilify®)	Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar 1 disorder in adolescents aged 13 years or over	Added to the additional list, for specialist prescribing only **RED**
	Nepafenac eye drops, 1% (Nevanac®)	Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients	Added as a prescribing note. The treatment is recommended for a total of 60 days. The first bottle will be provided by the hospital, the second by the GP **AMBER**
	Budesonide gastro-resistant granules, 9mg (Budenofalk®)	Induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or ascending colon	Added to the formulary, as a once daily alternative to 3mg capsules (given three times a day) **AMBER**
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:	Avanafil tablets, 50, 100, 200mg (Spedra®)	Treatment of erectile dysfunction in men	No submission received from manufacturer **BLACK**
The following drugs were approved by SMC but not by LJF, as the case for inclusion was not supported by local clinicians:	Adapelene + benzoyl peroxide gel (Epiduo® gel)	Cutaneous treatment of acne vulgaris when comedones, papules and pustules are present	Clinicians made no submission **BLACK**

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News from the MHRA

Domperidone

Domperidone is a dopamine antagonist with antiemetic properties.

A European review assessed the benefits and risks of domperidone following continued reports of cardiac side effects. The review confirmed a small increased risk of serious cardiac side effects. A higher risk was observed particularly in people older than 60 years, people taking daily oral domperidone doses of more than 30 mg, and those taking QT-prolonging medicines or CYP3A4 inhibitors at the same time as domperidone. For indications other than nausea and vomiting, the benefits were not considered to outweigh the cardiac risk. Based on the results of this review, the treatment advice for domperidone has been updated.

The overall safety profile of domperidone, and in particular its cardiac risk and potential interactions with other medications, should be taken into account if there is a clinical need to use it at doses or durations greater than those authorised (e.g., to control side effects of Parkinson's disease treatment in some patients).

Domperidone use in children is under further investigation. Domperidone licence-holders are required to conduct studies to provide further data to support domperidone efficacy in children.

Domperidone is now restricted to use in the relief of nausea and vomiting.

It should be used at the lowest effective dose for the shortest possible time.

Domperidone is now contraindicated in people:

- with conditions where cardiac conduction is, or could be, impaired
- with underlying cardiac diseases such as congestive heart failure
- receiving other medications known to prolong QT interval or potent CYP3A4 inhibitors
- with severe hepatic impairment

Patients with these conditions should have their treatment reviewed at their next routine appointment and be switched to an alternative treatment if required.

Oral formulations

- For adults and adolescents over 12 years of age and weighing 35 kg or more, the recommended maximum dose in 24 hours is 30 milligrams (dose interval: 10 milligrams up to three times a day).

	• In children under 12 years of age and weighing less than 35 kg, the recommended maximum dose in 24 hours is 0.75 mg/kg body weight (dose interval: 0.25 mg/kg body weight up to three times a day). *Suppository formulation* • Suppositories should only be used in adults and adolescents weighing 35 kg or more, the recommended maximum daily dose in 24 hours is 60 milligrams (dose interval: 30 milligrams twice a day). *Duration of treatment* • The maximum treatment duration should not usually exceed one week. • Patients currently receiving long-term treatment with domperidone should be reassessed at a routine appointment to advise on treatment continuation, dose change, or cessation. *Administration of liquid formulations* • Oral liquid formulations of domperidone should only be given via appropriately designed, graduated measuring devices (e.g., oral syringes for children and cups for adults and adolescents) to ensure dose accuracy.
Zolpidem	Zolpidem (Stilnoct®) is used to treat insomnia. Taking zolpidem is associated with a risk of impaired driving ability the next day. To reduce this risk, advise patients: • to take 10mg of zolpidem at bedtime and not to take it again the same night • not to drive, operate machinery, or work at heights until at least 8 hours after taking zolpidem • not to take zolpidem with alcohol, illicit drugs, or other central nervous system suppressants • not to drive, operate machinery or work at heights if they are still drowsy after taking zolpidem.

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NICE guidance

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

	Drug	Condition	Resume
TA309	Pemetrexed	Lung cancer (NSC non-squamous)	**Not recommended** as maintenance treatment for people with locally advanced or metastatic non-squamous non-small-cell lung cancer after therapy with pemetrexed and cisplatin.
TA310	Afatinib	Lung cancer (NSC EGFR-mutation positive)	**Recommended** as a possible treatment for adults with locally advanced or metastatic non-small-cell lung cancer if their cancer tests positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and they have not had a type of drug called an EGFR-TK inhibitor before.
TA311	Bortezomib	Multiple myeloma (induction therapy)	**Recommended** as a possible treatment (with dexamethasone ± thalidomide) for adults with multiple myeloma before having chemotherapy and stem cell transplantation, if their multiple myeloma has not been treated before.
CG179	Pressure ulcers		No specific guidance on dressings. Choice of dressing should be based on: • pain and tolerance • position of ulcer • amount of exudate frequency of dressing change

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