NHS Cumbria Clinical Commissioning Group

PRESCRIPTION PAD

The Newsletter of the Cumbria Area Prescribing Committee

September 2015 No. 37

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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

Generic Prescribing Statement	Cumbria Area Prescribing Committee supports generic prescribing of drugs, except when there are possible risks of variation of bioavailability, principally for modified release preparations. The use of branded generics is not supported. The full statement is available at http://medicines.necsu.nhs.uk/cumbria-apc/
Drugs for Dementia	Cumbria has consistently spent more on dementia drugs than the other CCGs in the NE and Cumbria over the last 3 years. This high cost is largely due to the proportion of galantamine prescribed. Only Northumberland CCG prescribes more galantamine per dementia patient, and Cumbria spend on donepezil is the lowest. **It is recommended that the drug of lowest acquisition costs (Donepezil) should be prescribed 1st line, Rivastigmine should be prescribed 2nd line.** **Memantine prescribed in combination with AChE inhibitors is now RAG status RED**
Updated Shared Care Guidelines	A new format for shared care guidelines has been agreed. Updated shared care guidelines do not include a patient details section. Secondary care clinicians will request GPs to prescribe under the SCG and GPs should access the latest version here http://medicines.necsu.nhs.uk/cumbria-shared-care-protocols/ **Enoxaparin** Changes include clarification of indications covered by shared care and those for which prescribing (and supply) should remain RED **Indication**: Extended treatment and prophylaxis of venous thromboembolism (VTE) in patients in whom oral anticoagulation is contra-indicated or not recommended [unlicensed indications] including: • Cancer patients with active disease and/or receiving chemotherapy • Patients with liver disease especially if prothrombin time is prolonged • Patients unable to comply with oral anticoagulant therapy • Patients awaiting completion of investigations before commencing an oral anticoagulant • All other indications not included in the RED list below The following indications are agreed RED (full supply from hospital): • Treatment and prophylaxis of VTE in pregnancy • Prophylaxis of VTE in oncology patients on VTE inducing therapy

	• Pre and post-operative use as replacement for warfarin in high risk patients i.e bridging therapy. (Primary care to prescribe if due to unforeseen circumstances patients require additional doses and cannot collect from the hospital). • Prophylaxis post-operatively e.g. TKR, THR, general surgery • Prophylaxis in patients with lower limb plaster cast **Mycophenolate Mofetil** Now includes recommendations on monitoring for recurrent infection and persistent cough or dyspnoea. All Shared Care Guidelines are available at http://medicines.necsu.nhs.uk/cumbria-shared-care-protocols/
Nabilone	The prescribing of Nabilone now has a RAG status **BLACK** Patients in North Cumbria can be referred to the pain service for review.
NOACs for Cardioversion	The prescribing of a NOAC for Cardioversion has been allocated a RAG status **RED** Secondary care will supply the quantity needed for the treatment of cardioversion, patients will then discuss the options for future treatment with their GP depending upon the outcome of their cardioversion.
Sevelamer & Lanthanum	The prescribing of these drugs remains with secondary care and the RAG status remains **RED**
Dosulepin Prescribing Guidance	Guidance has been produced to aid prescribers to review patients prescribed Dosulepin. The guidelines are available at http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/
Teraparatide	For the treatment of atypical fractures was not approved in line with the recommendation from Northern Treatment Advisory Group. **BLACK**
Metolazone	Use of Metolazone for heart failure (unlicensed indication) is **RED** It should be supplied by secondary care clinicians.

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Recommendations on New Medicines

	Drug	Licensed indication	Recommendation
The following drugs have been recommended as suitable for use	Alprostadil cream 3mg/g (Vitaros®)	Treatment of men ≥ 18 years of age with erectile dysfunction and who cannot receive or do not tolerate oral PDE5 inhibitors.	GREEN
	Magnesium aspartate dihydrate Sachets, 243mg (10mmoL) (Magnaspartate®)	Treatment and prevention of magnesium deficiency.	Should be used in preference to unlicensed preparations. GREEN

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News from the MHRA

SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin): risk of diabetic ketoacidosis (Drug safety update June 2015)	Test for raised ketones in patients with acidosis symptoms, even if plasma glucose levels are near-normal. When treating patients who are taking an SGLT2 inhibitor (canagliflozin, dapagliflozin or empagliflozin): • test for raised ketones in patients with symptoms of diabetic ketoacidosis (DKA); omitting this test could delay diagnosis of DKA • if you suspect DKA, stop SGLT2 inhibitor treatment • if DKA is confirmed, take appropriate measures to correct the DKA and to monitor glucose levels • inform patients of the symptoms and signs of DKA (see below); advise them to get immediate medical help if these occur • be aware that SGLT2 inhibitors are not approved for treatment of type 1 diabetes • please continue to report suspected side effects to SGLT2 inhibitors or any other medicines on a Yellow Card www.gov.uk/yellowcard **Reports of diabetic acidosis** Sodium-glucose co-transporter 2 (SGLT2) inhibitors are licensed for use in adults with type 2 diabetes to improve glycaemic control. Serious and life-threatening cases of DKA have been reported in patients taking SGLT2 inhibitors (canagliflozin, dapagliflozin or empagliflozin). In several cases, blood glucose levels were only moderately elevated (eg <14 mmol/L or 250 mg/dL), which is **atypical for DKA**. This atypical presentation could delay diagnosis and treatment. Therefore inform patients of the signs and symptoms of DKA (eg nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness) and test for raised ketones in patients with these signs and symptoms. Half of the cases occurred during the first 2 months of treatment. Some cases occurred shortly after stopping the SGLT2 inhibitor. One third of the cases involved off-label use in patients with type 1 diabetes. We remind you that this drug class is **not licensed** for the treatment of type 1 diabetes. The underlying mechanism for SGLT2 inhibitor-associated DKA has not been established. We are investigating this concern along with other EU medicines regulators. We will communicate further advice as appropriate once the investigation is complete. **SGLT2 inhibitors – medicines in this**
High-dose ibuprofen (≥2400mg/day): small increase in cardiovascular risk (Drug safety update June 2015)	EU review confirms that the cardiovascular risk of high-dose ibuprofen (≥2400mg/day) is similar to COX-2 inhibitors and diclofenac.

	When prescribing or dispensing ibuprofen: • avoid use of high-dose ibuprofen (≥2400 mg per day) in patients with established: o ischaemic heart disease o peripheral arterial disease o cerebrovascular disease o congestive heart failure (New York Heart Association [NYHA] classification II-III) o uncontrolled hypertension • review the treatment of patients with the above conditions who are taking high-dose ibuprofen at their next routine appointment • carefully consider the benefits and risks before starting long-term ibuprofen treatment for patients with significant risk factors for cardiovascular events (eg hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses are required • we remind you that ibuprofen is contraindicated in patients with severe heart failure • consider that these recommendations also apply to dexibuprofen (a high dose of dexibuprofen is 1200 mg or more per day, which is equivalent to 2400 mg of ibuprofen) • consider that no increase in cardiovascular risk is seen with ibuprofen at doses up to 1200 mg per day (the highest dose available over the counter) compared with not taking ibuprofen
Denosumab (Xgeva▼, Prolia); intravenous bisphosphonates: osteonecrosis of the jaw—further measures to minimise risk (Drug Safety Update July 2015)	Patient reminder cards about the risk of osteonecrosis of the jaw are being introduced; denosumab 120 mg is now contraindicated in patients with unhealed lesions from dental or oral surgery. Before prescribing denosumab or intravenous bisphosphonates: □ give patients the patient reminder card for their medicine1 □ explain the risk of osteonecrosis of the jaw and advise patients on precautions to take—advise patients to: o tell their doctor if they have any problems with their mouth or teeth before starting treatment; if they wear dentures they should make sure their dentures fit properly before starting treatment o maintain good oral hygiene and get routine dental check-ups during treatment o tell their doctor and dentist that they are receiving denosumab or an intravenous bisphosphonate if they need dental treatment or dental surgery o tell their doctor and dentist immediately if they have any problems with their mouth or teeth during treatment (eg loose teeth, pain, swelling, non-healing sores or discharge) □ Do not prescribe denosumab 120 mg (cancer indication) to patients with unhealed lesions from dental or oral surgery
Latanoprost (Xalatan): increased reporting of eye	Advise patients to tell their health professional if they experience severe eye irritation. When prescribing or dispensing the Xalatan brand of latanoprost: • advise patients to tell their health professional if they experience severe eye irritation • review treatment if patients mention severe eye irritation

irritation since reformulation (Drug Safety Update July 2015)	Xalatan is an eye-drop formulation of latanoprost. It is licensed for the reduction of intraocular pressure in adults and children with ocular hypertension and open angle glaucoma. In 2013 the Xalatan pH was reduced from 6.7 to 6.0 to allow for long-term storage at room temperature. Following this reformulation there has been an increase in the number of reports of eye irritation from across the EU. We received no Yellow Card reports of eye irritation in people using Xalatan in the year before the reformulation, compared with 22 reports in the year after reformulation.1 It is important that patients continue their treatment. Therefore advise patients to tell their health professional promptly (within a week) if they have eye irritation (eg excessive watering) severe enough to make them consider stopping treatment. Review treatment and prescribe a different formulation if necessary.

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NICE guidance

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

	Drug	Condition	Summary
TA346	Aflibercept	Treatment of diabetic macular oedema.	Aflibercept solution for injection is recommended as an option for treating visual impairment caused by diabetic macular oedema only if: the eye has a central retinal thickness of 400 micrometres or more at the start of treatment.RED
TA347	Nintedanib	For previously treated locally advanced, metastatic or locally recurrent non-small-cell lung cancer	Nintedanib in combination with docetaxel is recommended, within its marketing authorisation, as an option for treating locally advanced, metastatic or locally recurrent non-small-cell lung cancer of adenocarcinoma histology that has progressed after first-line chemotherapy.RED
TA348	Everolimus	Preventing organ rejection in liver transplantation	**Not recommended** within its marketing authorisation for preventing organ rejection in people having a liver transplant.BLACK
TA349	Dexamethasone intravitreal implant	Treatment of diabetic macular oedema	Dexamethasone intravitreal implant is recommended as an option for treating diabetic macular oedema only if: • the implant is to be used in an eye with an intraocular (pseudophakic) lens • the diabetic macular oedema does not respond to non-corticosteroid treatment, or such treatment is unsuitable RED
TA350	Secukinumab	For treating moderate to severe plaque psoriasis	Secukinumab is recommended, within its marketing authorisation, as an option for treating adults with plaque psoriasis only when: • the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 • the disease has failed to respond to standard systemic therapies, for example, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or

		these treatments are contraindicated or the person cannot tolerate them RED

	Condition	Recommendations
NG12	Suspected Cancer: Recognition and referral	The recommendations in this guideline have been organised into 3 separate sections to help healthcare professionals find the relevant information easily. This section includes the recommendations for investigation and referral organised by the site of the suspected cancer. The recommendations in this section have also been organised by symptoms and investigation findings in a separate section. There is also a section covering patient support, safety netting and the diagnostic process, which should be used in conjunction with this section.
NG13	Workplace policy and management practices to improve the health and well-being of employees.	This guideline makes recommendations on improving the health and wellbeing of employees, with a particular focus on organisational culture and context, and the role of line managers.
NG14	Melanoma: assessment and management	This guideline addresses areas where there is uncertainty or variation in practice. It contains recommendations on: • assessing and staging melanoma, including the use of sentinel lymph node biopsy • treating stages 0–IV melanoma, including adjuvant chemotherapy and immunotherapy • treating in-transit melanoma metastases • treating metastatic melanoma • follow-up after treatment for melanoma. The guideline also includes advice on managing vitamin D levels and drug therapy for intercurrent conditions in people diagnosed with melanoma.

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