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Area Drug and Therapeutics Committee Prescribing Supplement No 73 September 2013

In this issue –

ADTC UPDATES ON DRUGS REVIEWED BY THE SMC

The following new drugs have been reviewed by the Scottish Medicines Consortium in August 2013: -

Colour coding of Lanarkshire ADTC decisions about new medicines: -

Green = accepted for general use in Lanarkshire and added to the Joint Formulary

Orange = accepted for restricted use in Lanarkshire and added to the Joint Formulary only for the restricted use advised by the Scottish Medicines Consortium (SMC)

Light orange = Not added to the formulary due to the specialist nature of the treatment or pending specialist advice on formulary status. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.

Red = not accepted for use in Lanarkshire and not added to the Joint Formulary. A request to prescribe a drug in this category must be clinically justified by the prescriber.

Ms F Graham
NHSL Formulary Pharmacist
Prescribing Department
NHSL Headquarters
Kirklands
Fallside Road
BOTHWELL, G71 8BB

☎ 01698 858126/858127
Fax 01698 858271
✉ Fiona.graham@lanarkshire.scot.nhs.uk
or prescribing@lanarkshire.scot.nhs.uk

Date of SMC recommendation	Drug/product	SMC recommendation	Lanarkshire recommendation and ADTC comments
09/09/13 **No 891/13**	**aripiprazole 5mg, 10mg, 15mg, 30mg tablets, 10mg, 15mg orodispersible tablets, 1mg/mL oral solution (Abilify®) SMC No. (891/13)**	**ADVICE:** following a full submission **aripiprazole oral (Abilify®)** is accepted for restricted use within NHS Scotland. **Indication under review:** treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. **SMC restriction:** restricted to initiation and management under the supervision of a child/adolescent psychiatrist. Aripiprazole demonstrated superior efficacy to placebo in reducing manic symptoms at 4 weeks. Aripiprazole has not been directly compared to other atypical antipsychotics	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**
09/09/13 **No 814/12**	**caffeine citrate, 20mg/mL, solution for infusion and oral solution (Peyona®)**	**ADVICE**: following a full submission **caffeine citrate (Peyona®)** is accepted for use within NHS Scotland. **Indication under review:** treatment of primary apnoea of premature newborns. In premature infants with apnoea of prematurity, caffeine citrate significantly reduced apnoeic episodes compared with placebo. A long-term placebo-controlled study demonstrated a reduced risk of disabilities relevant to these infants. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of caffeine citrate (Peyona®). This SMC advice is contingent upon the continuing availability of the PAS or an equivalent or lower list price in NHS Scotland.	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**

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09/09/13 **No 903/13**	**lixisenatide 10microgram/0.2mL, 20microgram/0.2mL solution for injection in pre-filled disposable pen (Lyxumia®)**	**ADVICE**: following a full submission **lixisenatide (Lyxumia®)** is accepted for restricted use within NHS Scotland. **Indication under review:** treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. **SMC restriction:** to use in patients for whom a glucagon-like protein-1 (GLP-1) agonist is appropriate, as an alternative to existing GLP-1 agonists. Lixisenatide reduces glycosylated haemoglobin (HbA1c) and body weight compared with placebo when used in combination with oral antidiabetic drugs or in combination with basal insulin.	**Not added to the formulary due pending advice on formulary status. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**
09/09/13 **No 894/13**	**rituximab 100mg, 500mg solution for infusion (MabThera®)**	**ADVICE**: following a full submission **rituximab (MabThera®)** is accepted for restricted use within NHS Scotland. **Indication under review:** In combination with glucocorticoids for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener's) (GPA) and microscopic polyangiitis (MPA). **SMC restriction:** to use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide. One course of rituximab (an intravenous infusion weekly for four weeks) was non-inferior to three to six months of oral cyclophosphamide for the proportion of patients achieving remission at six months. The study was conducted in patients with severe proteinase 3- or myeloperoxidase-antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis who were treatment-naïve or previously treated.	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**

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09/09/13 **No 893/13**	**rifaximin 550mg film-coated tablets (Targaxan®)**	**ADVICE**: following a full submission **rifaximin (Targaxan®)** is accepted for use within NHS Scotland. **Indication under review:** reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients _18 years of age. In a double-blind randomised controlled study of six months duration, rifaximin was superior to placebo for the primary outcome of time to first overt breakthrough episode of HE.	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**
09/09/13 **No 892/13**	**ocriplasmin, 0.5mg/0.2 mL, concentrate for solution for injection**	**ADVICE**: following a full submission **ocriplasmin (Jetrea®)** is not recommended for use within NHS Scotland. **Indication under review:** In adults for the treatment of vitreomacular traction, including when associated with macular hole of diameter less than or equal to 400 microns. In two randomised, controlled double-masked studies, significantly more patients treated with ocriplasmin than placebo achieved resolution of vitreomacular traction which may correlate with improved visual acuity. The submitting company did not present a sufficiently robust economic case to gain acceptance by SMC. The licence holder has indicated their intention to resubmit.	**Not accepted for use in Lanarkshire and not added to the Joint Formulary. A request to prescribe a drug in this category must be clinically justified by the prescriber.**

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09/09/13 **No 896/13**	**medroxyprogesterone acetate 104mg/0.65mL suspension for subcutaneous depot injection (Sayana® Press)**	**ADVICE**: following an abbreviated submission **medroxyprogesterone acetate injection (Sayana® Press)** is accepted for use within NHS Scotland. **Indication under review:** for long-term female contraception. Each subcutaneous injection prevents ovulation and provides contraception for at least 13 weeks (+/- 1 week). However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year. In adolescents (12-18years), use of medroxyprogesterone acetate injection is only indicated when other contraceptive methods are considered unsuitable or unacceptable, due to unknown long-term effects of bone loss associated with medroxyprogesterone acetate injection during the critical period of bone accretion. Sayana® Press contains medroxyprogesterone acetate for subcutaneous injection at a similar cost to the existing deep intramuscular injection.	**Not added to the formulary due to the pending advice on formulary status. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**
09/09/13 **No 901/13**	**etravirine 25mg, 100mg, 200mg tablets (Intelence®)**	**ADVICE**: following an abbreviated submission **etravirine (Intelence®)** is accepted for restricted use within NHS Scotland. **Indication under review:** in combination with a boosted protease inhibitor and other antiretroviral medicinal products, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced paediatric patients from 6 years to less than 18 years of age. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric HIV. SMC has previously accepted etravirine for use in combination with a boosted protease inhibitor and other antiretroviral medicinal products for the treatment of HIV-1 infection in antiretroviral treatment experienced adult patients. Etravirine is listed in the British National Formulary for Children 2012-2013 for the treatment of HIV infection.	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**

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09/09/13 **No 902/13**	**raltegravir 25mg, 100mg chewable and 400mg film-coated tablets (Isentress®)**	**ADVICE**: following an abbreviated submission **raltegravir (Isentress®)** is accepted for restricted use within NHS Scotland. **Indication under review:** in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adolescents and children aged 2 to 17 years. **SMC restriction:** to patients who are intolerant or resistant to non-nucleoside reverse transcriptase inhibitors (NNRTIs) or protease inhibitors (PIs) or when these options are compromised due to drug-drug interactions; raltegravir should to be prescribed under the supervision of specialists in paediatric HIV. The chewable and film-coated tablets are not bioequivalent and therefore are not interchangeable. SMC has previously accepted raltegravir 400mg film-coated tablets for restricted use in combination with other anti-retroviral medicinal products for the treatment of HIV-1 infection in adult patients. Raltegravir is listed in the British National Formulary for Children for the treatment of HIV infection.	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**
09/09/13 **No 900/13**	**tenofovir disoproxil (as fumarate) 123mg, 163mg, 204mg film-coated tablets (Viread®)**	**ADVICE:** following an abbreviated submission **tenofovir disoproxil (Viread®)** is accepted for restricted use within NHS Scotland. **Indication under review:** in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 6 to < 12 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. **SMC restriction:** to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of HIV infection.	**Not added to the formulary due to the specialist nature of the treatment. Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**

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09/09/13 **No 905/13**	**tenofovir disoproxil (as fumarate) 33mg/g oral granules (Viread®)**	**ADVICE**: following an abbreviated submission **tenofovir disoproxil (Viread®)** is accepted for restricted use within NHS Scotland. **Indication under review:** *HIV-1 infection* - in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected paediatric patients, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents, from 2 to < 6 years of age, and above 6 years of age for whom a solid dosage form is not appropriate; and, in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults for whom a solid dosage form is not appropriate. *Hepatitis B infection* - for the treatment of chronic hepatitis B in adults for whom a solid dosage form is not appropriate with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis; decompensated liver disease; and, for the treatment of chronic hepatitis B in adolescents 12 to <18 years of age for whom a solid dosage form is not appropriate with compensated liver disease and evidence of immune active disease, i.e. active viral replication, persistently elevated serum ALT levels and histological evidence of active inflammation and/or fibrosis. **SMC restriction:** in patients <18 years, to be prescribed under the supervision of specialists in paediatric infectious diseases. SMC has previously accepted tenofovir disoproxil for use in combination with other antiretroviral agents in HIV infected patients over 18 years of age experiencing virological failure. SMC has previously accepted tenofovir disoproxil for use in the treatment of chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis and in patients with decompensated liver disease. Tenofovir disoproxil is listed in the British National Formulary for Children 2012-2013 for the treatment of hepatitis B infection and HIV infection.	**Not added to the formulary due to the specialist nature of the treatment.** **Non formulary use is acceptable if the drug is used according to SMC recommendations and local protocols.**

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09/09/13 **No 915/13**	**eculizumab (Soliris®) 300 mg concentrate for solution for infusion**	**ADVICE**: in the absence of a submission from the holder of the marketing authorisation **eculizumab (Soliris ®)** is not recommended for use within NHS Scotland. **Indication under review:** in children for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.	**not accepted for use in Lanarkshire and not added to the Joint Formulary. A request to prescribe a drug in this category must be clinically justified by the prescriber.**

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