NEW DRUG RECOMMENDATIONS
AUGUST/SEPTEMBER 2013

NHS Greater Glasgow and Clyde

Section 1: Medicines accepted by SMC – Included in Formulary (Major changes)

Medicine name:	Crizotinib, hard capsule (Xalkori®) *Pfizer Ltd*	Reason for consideration:	New medicine
Indication under review:	Treatment of adults with previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).		
SMC/ HIS reference:	SMC 865/13 [Resubmission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In a phase III clinical study in patients with previously treated anaplastic lymphoma kinase (ALK)-positive advanced NSCLC, crizotinib significantly increased progression-free survival compared with standard chemotherapy. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of crizotinib. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question pending protocol.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Lixisenatide pre-filled disposable pen (Lyxumia®) *Sanofi*	Reason for consideration:	New medicine
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/ HIS reference:	SMC 903/13 [Full Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist initiation as a third-line agent, either in combination with metformin and a sulphonylurea or metformin and a thiazolidinedione, or as adjunctive therapy to basal insulin in patients for whom a glucagon-like protein-1 (GLP-1) agonist is appropriate.		✓R
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:
- ✓ Included on Formulary
- ✓R Included on Formulary with restrictions
- ✗ Not included on Formulary
- Ⓢ Specialist initiation only
- Ⓢ Specialist use only

Medicine name:	Nalmefene (Selincro®) *Lundbeck Limited*	Reason for consideration:	New medicine
Indication under review:	The reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. Nalmefene should only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. Nalmefene should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.		
SMC/ HIS reference:	SMC 917/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In a post hoc analysis of two pivotal phase III studies representing the licensed population, nalmefene was shown to significantly reduce alcohol intake compared with placebo, measured as a reduction in heavy drinking days and total alcohol consumption over a six month period.		
FND recommendation:	Not included in the GGC Total Formulary for the indication in question pending discussion with the relevant specialists		✘
ADTC Decision 21/10/13	Included in the GGC Total Formulary for the indication in question. Nalmafene should only be prescribed as part of a full package of care including the provision of continuous psychosocial support by appropriate NHS personnel and should be reviewed regularly.		

Medicine name:	Rifaximin (Targaxan®) *Norgine Pharmaceuticals Ltd*	Reason for consideration:	New indication
Indication under review:	Reduction in recurrence of episodes of overt hepatic encephalopathy (HE) in patients **≥18 years of age.**		
SMC/ HIS reference:	SMC 893/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the Total Formulary for the indication in question restricted to specialist initiation by a consultant gastroenterologist.		✓ R
ADTC Decision 21/10/13	AGREED		

Section 2: Medicines accepted by SMC – Included in Formulary (Minor changes)

Medicine name:	Bimatoprost and Timolol eye drops (Ganfort® Unit Dose Preservative Free) *Allergan Ltd*	Reason for consideration:	Product update
Indication under review:	For the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.		
SMC/ HIS reference:	SMC 906/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	SMC restriction: to use in patients who have proven sensitivity to preservatives. SMC has previously accepted preserved bimatoprost plus timolol eye-drops for use in NHS Scotland. This preparation is more expensive than the equivalent multi-dose eye drop preparation with preservative.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist initiation in patients who have proven sensitivity to the preservative benzalkonium chloride.		✓R
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Medicine name:	Botulinum toxin type A (Botox®) *Allergan Ltd*	Reason for consideration:	New indication
Indication under review:	Management of urinary incontinence in adult patients with neurogenic detrusor overactivity due to subcervical spinal cord injury (traumatic or non-traumatic) or multiple sclerosis, who are not adequately managed with anticholinergics; patients should be already catheterising or willing and able to catheterise if required.		
SMC/ HIS reference:	SMC 916/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In two phase III, double-blind, placebo-controlled studies, in which all patients received best supportive care, botulinum toxin type A 200 units (licensed dose) was significantly superior to placebo for mean reduction in weekly urinary incontinence episodes, from baseline to week six. There are currently limited data on re-treatment.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Carglumic Acid (Carbaglu®) *Orphan Europe (UK) Limited*	Reason for consideration:	New indication
Indication under review:	Hyperammonaemia due to isovaleric acidaemia, methylmalonic acidaemia and propionic acidaemia.		
SMC/ HIS reference:	SMC 889/13 [Full Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	The available clinical evidence for carglumic acid, although limited, suggests that plasma ammonia is reduced rapidly to non-toxic levels in life-threatening situations where rapid initiation of treatment is essential.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Granisetron transdermal patch (Sancuso®) *ProStrakan Ltd*	Reason for consideration:	Product update
Indication under review:	In adults for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral anti-emetic administration is complicated by factors making swallowing difficult.		
SMC/ HIS reference:	SMC 895/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	Granisetron 3.1mg / 24 hours transdermal patch is slightly more expensive than the oral formulation. It provides an alternative option in patients who have difficulty swallowing oral medication.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist initiation only in accordance with regional anti-emetic protocol.		✓R
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:
- ✓ Included on Formulary
- ✓R Included on Formulary with restrictions
- ✗ Not included on Formulary
- Ⓢ Specialist initiation only
- Ⓢ Specialist use only

Medicine name:	Medroxyprogesterone acetate subcutaneous depot injection (Sayana® Press) *Pfizer Ltd*	Reason for consideration:	New presentation
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.		
SMC/ HIS reference:	SMC 896/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	In adolescents (12-18 years), 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.		
FND recommendation:	Included in the Preferred List for the indication in question.		✓
ADTC Decision 21/10/13	AGREED		

Medicine name:	Rituximab (MabThera®) *Roche Products Limited*	Reason for consideration:	New indication
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/ HIS reference:	SMC 894/12 [Full Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Total Formulary for the indication in question. Restricted to specialist use in patients who have relapsed following treatment with cyclophosphamide or who are intolerant to or unable to receive cyclophosphamide.		✓R
ADTC Decision 21/10/13	AGREED		

Section 3: Medicines accepted by SMC – Not included in Formulary

Section 4: Medicines accepted by SMC – Not included pending protocol/consultation

Section 5: Medicines not recommended by SMC

Medicine name:	Eculizumab (Soliris®) *Alexion Pharma UK Ltd*	Reason for consideration:	New indication
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.		
SMC/ HIS reference:	SMC 915/13 [Non Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Not included in the GGC Paediatric Formulary for the indication in question.		✗

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Medicine name:	Imatinib (Glivec®) *Novartis Pharmaceuticals UK Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment of paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy.		
SMC/ HIS reference:	SMC 923/13 [Non Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Not included in the GGC Paediatric Formulary for the indication in question.		✘

Medicine name:	Ocriplasmin (Jetrea®) *ThromboGenics NV*	Reason for consideration:	New medicine
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.		
SMC/ HIS reference:	SMC 892/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Medicine name:	Pertuzumab (Perjeta®) *Roche Products Limited*	Reason for consideration:	New medicine
Indication under review:	For use in combination with trastuzumab and docetaxel in adult patients with human epidermal growth factor-2 (HER2)-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.		
SMC/ HIS reference:	SMC 897/13 [Full Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	Addition of pertuzumab to current first-line treatment (trastuzumab plus docetaxel) significantly increased progression-free and overall survival for women with HER2-positive metastatic breast cancer. The submitting company did not present a sufficiently robust economic analysis and in addition its justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by SMC.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Medicine name:	Vismodegib (Erivedge®) *Roche Products Ltd*	Reason for consideration:	New medicine
Indication under review:	• Symptomatic metastatic basal cell carcinoma • Locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy.		
SMC/ HIS reference:	SMC 924/13 [Non Submission]		
Summary of advice:	Not recommended for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Not included in the GGC Adult Formulary for the indication in question.		✘

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
S Specialist initiation only
S Specialist use only

Section 6: Medicines accepted by SMC – Consideration in GGC Paediatric Formulary only

Medicine name:	Aripiprazole (Abilify®) *Otsuka Pharmaceutical (UK) Ltd*	Reason for consideration:	New indication
Indication under review:	Treatment up to 12 weeks of moderate to severe maniac episodes in Bipolar Disorder I in adolescents aged 13 years and older.		
SMC/ HIS reference:	SMC 891/13 [Full Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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, none of which are licensed for this indication although they are used off-label in clinical practice.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist initiation and management under the supervision of a child/ adolescent psychiatrist.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Caffeine Citrate (Peyona®) 20mg/ml *Chiesi Limited*	Reason for consideration:	New presentation
Indication under review:	Treatment of primary apnoea of premature newborns.		
SMC/ HIS reference:	SMC 814/12 [Full Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Etravirine (Intelence®) *Janssen-Cilag*	Reason for consideration:	Product update
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/ HIS reference:	SMC 901/13 [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to use by paediatric HIV specialists.		✓R
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:
- ✓ Included on Formulary
- ✓R Included on Formulary with restrictions
- ✗ Not included on Formulary
- Ⓢ Specialist initiation only
- Ⓢ Specialist use only

Medicine name:	Raltegravir (Isentress®) *MSD Ltd*	Reason for consideration:	Product update
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/ HIS reference:	SMC 902/13/ [Abbreviated Submission]		
Summary of advice:	Accepted for use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use by paediatric HIV specialists in 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.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Tenofovir Disoproxil (as fumarate) 123mg, 163mg, 204 mg tablets (Viread®) *Gilead Sciences Ltd*	Reason for consideration:	Product update
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/ HIS reference:	SMC 900/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to use by paediatric HIV specialists.		✓R
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:

✓ Included on Formulary
✓R Included on Formulary with restrictions
✗ Not included on Formulary
Ⓢ Specialist initiation only
Ⓢ Specialist use only

Medicine name:	Tenofovir Disoproxil (as fumarate) 245mg tablets (Viread®) *Gilead Sciences Ltd*	Reason for consideration:	Product update
Indication under review:	*HIV-1 infection* - in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infected paediatric and adolescent patients aged 12 to < 18 years, with nucleoside reverse transcriptase inhibitor (NRTI) resistance or toxicities precluding the use of first line agents. *Hepatitis B infection* - for the treatment of chronic hepatitis B in adolescents aged 12 to <18 years of age 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/ HIS reference:	SMC 904/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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. 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.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to use by paediatric HIV specialists.		✓R
ADTC Decision 21/10/13	AGREED		

Medicine name:	Tenofovir Disoproxil (as fumarate) 33mg/oral granules (Viread®) *Gilead Sciences Ltd*	Reason for consideration:	Product update
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/ HIS reference:	SMC 905/13 [Abbreviated Submission]		
Summary of advice:	Accepted for restricted use within NHS Scotland		
SMC/HIS restriction and comments:	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.		
FND recommendation:	Ⓢ Included in the GGC Paediatric Formulary for the indication in question. Restricted to specialist use under the supervision of specialists in paediatric infectious diseases.		✓R
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:
- ✓ Included on Formulary
- ✓R Included on Formulary with restrictions
- ✗ Not included on Formulary
- Ⓢ Specialist initiation only
- Ⓢ Specialist use only

Section 7: Other Formulary decisions – Appeals, reviews, NICE/SIGN guidance

Medicine name:	Ropivacaine hydrochloride (Naropin®) *Astra Zeneca*	Indication:	The production of local or regional anaesthesia for surgery and for acute pain management. Peri-operative intra/peri-articular infiltration for post-operative pain management.
Reason for consideration:	Formulary Appeal	SMC decision:	N/A
FND recommendation, restrictions on use and comments: Not included in the GGC Total Formulary at the present time. The appeal had wider implications that the addition of a medicine to the local Formulary. The first step should be a formal evaluation of the Enhanced Recovery Programme (ERP) by the Surgery & Anaesthetic Directorate. Should that be approved and for wider implementation then the associated medicine implications can be progressed, included preferred anaesthetic choice(s). There is no objection in principle to adding anaesthetics to the GGC Formulary for the proposed use. However, the post-operative use of oxycodone is not recommended by SMC and remains non-Formulary.			✘
ADTC Decision 21/10/13	AGREED		

Key to recommendations and symbols:
✓ Included on Formulary
✓R Included on Formulary with restrictions
✘ Not included on Formulary
S Specialist initiation only
S Specialist use only