NEW DRUG RECOMMENDATIONS

JULY 2011

NHS Greater Glasgow and Clyde

Section 1: Medicines accepted by SMC – Major Changes to Formulary

Medicine name:	**Lenalidomide (Revlimid®)** *Celgene Europe Ltd*	Indication:	**In combination with dexamethasone, for the treatment of multiple myeloma in patients who have received at least one prior therapy.**
Reason for consideration:	**New medicine**	SMC decision:	**Accepted for restricted use in NHS Scotland (SMC 441/08) [Resubmission] [Deferred Decision]**
FND recommendation, restrictions on use and comments:			✓R
Add to Total Formulary (Previously pending Board Financial Plan for 2011/12). Restricted to use in accordance with regional protocol. Lenalidomide plus dexamethasone significantly increased the time to progression compared with dexamethasone alone in multiple myeloma patients who had been treated with at least one prior therapy. The health economic case was demonstrated only for a sub-population of patients within the licensed indication. Taking into account the orphan drug status of lenalidomide and the substantial survival benefit it appears to offer SMC concluded that the economic case was demonstrated.			
ADTC decision 08/0811	AGREED		

Medicine name:	**Histrelin acetate implant (Vantas®)** *Orion Pharma (UK) Ltd.*	Indication:	**Palliative treatment of advanced prostate cancer**
Reason for consideration:	**New medicine**	SMC decision:	**Accepted for restricted use in NHS Scotland (SMC 557/09) [Deferred Decision]**
FND recommendation, restrictions on use and comments:			✓R
Add to Total Formulary. Restricted to use in accordance with Clinical Management Guideline In a single-arm study, histrelin provided effective suppression of testosterone levels in patients with advanced prostate cancer. It requires less frequent administration than other leutenising hormone releasing hormone LHRH) agonists. Other LHRH agonists are available at a lower acquisition cost.			
ADTC decision 08/08/09	AGREED		

Medicine name:	**Degarelix (Firmagon®)** *Ferring Pharmaceuticals Ltd*	Indication:	**Treatment of adult male patients with advanced hormone-dependent prostate cancer.**
Reason for consideration:	**New medicine**	SMC decision:	**Accepted for use within NHS Scotland (SMC 560/09) [Resubmission] [Deferred Decision]**
FND recommendation, restrictions on use and comments:			✓R
Add to Total Formulary (Arrangements in place for PAS) Restricted to use in accordance with regional protocol. In one study that included patients with all stages of prostate cancer, degarelix was shown to be non-inferior to a luteinising hormone releasing hormone (LHRH) agonist in suppressing testosterone levels over a one year treatment period without an initial testosterone flare. This SMC advice takes account of the benefits of a patient access scheme (PAS) that improves the cost-effectiveness of degarelix. This SMC advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.			
ADTC decision 08/0811	AGREED		

Key to recommendations and symbols:
- ✓ Added to Formulary
- ✓R Added to Formulary with restrictions
- ✗ Not added to Formulary
- Specialist initiation only
- Specialist use only
- ? Awaiting final decision

Medicine name:	**Pazopanib (Votrient®)** *GlaxoSmithKline UK*	Indication:	**First-line treatment of advanced renal cell carcinoma (RCC) and for patients who have received prior cytokine therapy for advanced disease.**
Reason for consideration:	**New medicine**	SMC decision:	**Accepted for use within NHS Scotland (SMC 676/11) [Deferred Decision]**

FND recommendation, restrictions on use and comments:

Add to Total Formulary (Previously pending Board Financial Plan for 2011/12). Arrangements in place for PAS. Restricted to use in accordance with regional protocol.

The SMC restriction is for first-line treatment of advanced RCC.

Pazopanib was superior to placebo for the primary endpoint, progression free survival, in the whole population and the treatment naïve and cytokine pre-treated sub-groups. An indirect comparison demonstrated that pazopanib had similar efficacy to the main comparator.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pazopanib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.

✓R

ADTC decision 08/08/11	AGREED

Medicine name:	**Retigabine (Trobalt®)** *GlaxoSmithKline*	Indication:	**Adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy.**
Reason for consideration:	**New medicine**	SMC decision:	**Accepted for restricted use within NHS Scotland (SMC 712/11)**

FND recommendation, restrictions on use and comments:

Add to Total Formulary
Restricted to patients with refractory disease and initiation by physicians who have appropriate experience in the treatment of epilepsy.

The SMC restriction was for patients in with refractory epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy.

In two placebo-controlled studies in patients with refractory epilepsy retigabine was superior to placebo in terms of the proportion of patients experiencing ≥ 50% reduction in partial seizure frequency per 28 days. An indirect comparison indicates that retigabine has similar efficacy to two other antiepileptic drugs used as adjunctive therapy.

✓R

ADTC decision 08/08/11	AGREED

Section 2: Medicines accepted by SMC – Minor or no changes to Formulary

Medicine name:	**Rituximab (MabThera®)** *Roche Products Limited*	Indication:	**Treatment of follicular lymphoma in patients responding to induction therapy.**
Reason for consideration:	**New indication**	SMC decision:	**Accepted for restricted use within NHS Scotland (SMC 675/11) [Deferred Decision]**

FND recommendation, restrictions on use and comments:

Acknowledge new indication (Total Formulary). (Previously pending Board Financial Plan for 2011/12). Restricted to use in accordance with regional protocol.

The SMC restriction is use for maintenance treatment in follicular lymphoma patients who have responded to induction with rituximab plus chemotherapy.

Rituximab significantly increased progression free survival following a response to induction therapy in patients with previously untreated follicular lymphoma compared with observation alone. Longer follow up is required to establish benefit in overall survival.

✓R

ADTC decision 08/08/11	AGREED

Key to recommendations and symbols:

✓	Added to Formulary	Ⓢ	Specialist initiation only
✓R	Added to Formulary with restrictions	Ⓢ	Specialist use only
✗	Not added to Formulary	?	Awaiting final decision

Medicine name:	**Sunitinib (Sutent®)** *Pfizer Limited*	Indication:	**Treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours with disease progression in adults.**
Reason for consideration:	**New indication**	SMC decision:	**Accepted for restricted use in NHS Scotland (SMC 698/11) [Deferred Decision]**

FND recommendation, restrictions on use and comments:

Acknowledge new indication (Total Formulary). [Arrangements in place for PAS].
Restricted to use in accordance with regional protocol.

Treatment with sunitinib improved progression free survival compared with placebo in patients with well-differentiated neuroendocrine carcinoma of the pancreas who were receiving best supportive care, including somatostatin analogues if required for symptomatic control.

This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of sunitinib. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland.

✓R

ADTC decision 08/0811	AGREED

Medicine name:	**Darunavir (Prezista®)** *Janssen*	Indication:	**Darunavir 800mg once daily co-administered with low dose ritonavir (100mg once daily) for the treatment of HIV-1 infection in antiretroviral therapy experienced adults with no darunavir resistance associated mutations and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥100 cells/mm³.**
Reason for consideration:	**New indication**	SMC decision:	**Accepted for use within NHS Scotland (SMC 707/11) [Resubmission]**

FND recommendation, restrictions on use and comments:

Acknowledge new indication (Total Formulary)
Restricted to use by HIV specialists.

Darunavir 800mg/ritonavir 100mg once daily was demonstrated to be non inferior to darunavir 600mg/ritonavir 100mg twice daily, when administered with an optimised background regimen that consisted of at least two nucleoside reverse transcriptase inhibitors in treatment experienced HIV infected patients.

✓R

ADTC decision 08/0811	AGREED

Medicine name:	**Triptorelin pamoate 22.5mg injection (Decapeptyl SR®)** *Ipsen Ltd*	Indication:	• **Treatment of patients with locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration.** • **Treatment of metastatic prostate cancer.**
Reason for consideration:	**New strength**	SMC decision:	**Accepted for restricted use in NHS Scotland (SMC 705/11) [Deferred Decision]**

FND recommendation, restrictions on use and comments:

Acknowledge new strength (Total Formulary).
Restricted to use in accordance with regional protocol.

This new preparation of triptorelin allows 6-monthly administration (as triptorelin pamoate in a 22.5mg dose). Triptorelin 11.25mg (as acetate) is administered every 3 months and has previously been accepted by SMC. Bioequivalence of the pamoate and acetate salts has been demonstrated and the new preparation is cost neutral.

Note: The indication for triptorelin 11.25mg formulation was reworded in 2007 to achieve consistency Europe-wide and now reads as per the indication for triptorelin 22.5mg.

✓R

ADTC decision 08/0811	AGREED

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✗ Not added to Formulary
Specialist initiation only
Specialist use only
? Awaiting final decision

Section 3: Medicines not recommended by SMC

Medicine name:	**Trabectedin (Yondelis®)** *Pharma Mar, SA Sociedad Unipersonal*	Indication:	**Treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.**
Reason for consideration:	**New medicine**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 452/08) [2nd Resubmission]**
FND recommendation, restrictions on use and comments: **Not added to the Formulary.** In a phase II randomised study in patients with advanced leiomyosarcoma and liposarcoma in which two trabectedin dose schedules were compared, the licensed 3-weekly schedule was superior to the alternative schedule for the primary endpoint, time to progression. The manufacturer's justification of the treatment's cost in relation to its health benefits was not sufficient and in addition, the manufacturer did not present a sufficiently robust economic case to gain acceptance by SMC.			✘

Medicine name:	**Glucosamine sulphate (Glusartel®)** *Rottapharm Madaus*	Indication:	**Relief of symptoms in mild to moderate osteoarthritis of the knee.**
Reason for consideration:	**New medicine**	SMC decision:	**Not recommended for use in NHS Scotland (SMC 647/10) [Resubmission]**
FND recommendation, restrictions on use and comments: **Not added to Formulary.** In a placebo and active-comparator study, glucosamine sulphate 1,500mg once daily was significantly better than placebo in the treatment of symptoms associated with osteoarthritis of the knee. Overall the submitting company did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.			✘

Medicine name:	**Prucalopride ('Resolor®)** *Shire/Movetis*	Indication:	**For symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.**
Reason for consideration:	**New medicine**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 653/10) [Resubmission]**
FND recommendation, restrictions on use and comments: **Not added to the Formulary.** Overall the manufacturer did not present a sufficiently robust clinical and economic analysis to gain acceptance by SMC.			✘

Medicine name:	**Ranibizumab (Lucentis®)** *Novartis Pharmaceuticals UK Ltd*	Indication:	**Treatment of visual impairment due to diabetic macular oedema in adults.**
Reason for consideration:	**New indication**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 711/11)**
FND recommendation, restrictions on use and comments: **Not added to the Formulary for this indication.** Ranibizumab significantly improved visual acuity over 12 months compared with standard laser photocoagulation treatment. The manufacturer's justification of the treatment's health benefits in relation to its cost was not sufficient and in addition, the manufacturer did not present a sufficiently robust economic analysis to gain acceptance by SMC.			✘

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✘ Not added to Formulary
S Specialist initiation only
S Specialist use only
? Awaiting final decision

Medicine name:	**Paliperidone (Xeplion®) Long Acting Injection** *Janssen-Cilag Ltd*	Indication:	**Maintenance treatment of schizophrenia in adult patients stabilised with paliperidone or risperidone. In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, it may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.**
Reason for consideration:	**New medicine**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 713/11)**
FND recommendation, restrictions on use and comments: **Not added to the Formulary.** Overall the manufacturer did not present a sufficiently robust clinical and economic case to gain acceptance by SMC.			✘

Medicine name:	**Collagenase clostridium histolyticum (Xiapex®)** *Pfizer Ltd*	Indication:	**Treatment of Dupuytren's contracture in adult patients with a palpable cord.**
Reason for consideration:	**New medicine**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 715/11 [Resubmission]**
FND recommendation, restrictions on use and comments: **Not added to the Formulary.** Collagenase clostridium histolyticum compared to placebo significantly reduces primary joint contracture in adults with Dupuytren's contracture and a palpable cord. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.			✘

Medicine name:	**Glucosamine sulphate (Dolenio®)** *Blue Bio Pharmaceuticals Ltd*	Indication:	**Symptomatic treatment of mild to moderate osteoarthritis (OA) of the knee**
Reason for consideration:	**New indication**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 729/11) [Non-submission]**
FND recommendation, restrictions on use and comments: **Not added to the Formulary for this indication.** 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.			✘

Medicine name:	**Bilastine (Ilaxten®)** *A Menarini Pharma UK SRL*	Indication:	**Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria**
Reason for consideration:	**New medicine**	SMC decision:	**Not recommended for use within NHS Scotland (SMC 730/11) [Non-submission]**
FND recommendation, restrictions on use and comments: **Not added to the Formulary.** The holder of the marketing authorisation has not made a submission to SMC regarding this product. As a result we cannot recommend its use within NHSScotland.			✘

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✘ Not added to Formulary
S Specialist initiation only
S Specialist use only
? Awaiting final decision

Section 4: Medicines accepted by SMC – Decisions deferred

Medicine name:	**Mifamurtide (Mepact®)** *Takeda UK and Ireland Ltd*	Indication:	**In combination with post-operative multi-agent chemotherapy for the treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection, in children, adolescents and young adults. Safety and efficacy have been assessed in studies of patients 2 to 30 years of age at initial diagnosis.**
Reason for consideration:	**New medicine**	SMC decision:	**Accepted for use in NHS Scotland (SMC 621/10) [Resubmission]**
FND recommendation, restrictions on use and comments: **Deferred to allow consultation with the Regional Cancer Advisory Group.** **Interim non-Formulary status.** Mifamurtide has been shown to increase overall survival compared with multi-agent chemotherapy alone in patients aged up to 30 years with newly-diagnosed resectable osteosarcoma. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of mifamurtide. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.			**?**
ADTC decision 08/08/11			

Medicine name:	**Nilotinib 150mg hard capsules (Tasigna®)** *Novartis Pharmaceuticals UK Ltd*	Indication:	**For the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myelogenous leukaemia (CML) in the chronic phase.**
Reason for consideration:	**New indication**	SMC decision:	**Accepted for use in NHS Scotland (SMC 709/11)**
FND recommendation, restrictions on use and comments: **Deferred to allow consultation with the Regional Cancer Advisory Group.** **Interim non-Formulary status.** First-line treatment with nilotinib in newly diagnosed patients has resulted in significantly higher molecular and cytogenetic response rates compared to the standard tyrosine kinase inhibitor. Further longer term follow-up data are needed to confirm the duration of this response and assess the impact on disease progression and overall survival. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of nilotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland.			**?**
ADTC decision 08/08/11			

Medicine name:	**Capecitabine (Xeloda®)** *Roche Production Limited*	Indication:	**The adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer in combination with oxaliplatin.**
Reason for consideration:	**New indication**	SMC decision:	**Accepted for use in NHS Scotland (SMC 716/11)**
FND recommendation, restrictions on use and comments: **Deferred to allow consultation with the Regional Cancer Advisory Group.** **Interim non-Formulary status.** At 55 months, disease free survival was significantly increased for capecitabine plus oxaliplatin-treated patients compared with a recognised regimen containing a fluoropyramidine in the adjuvant treatment of patients with completely resected stage III (Dukes' C) colon cancer.			**?**
ADTC decision 08/08/11			

Key to recommendations and symbols:

- ✓ Added to Formulary
- ✓R Added to Formulary with restrictions
- ✗ Not added to Formulary
- Ⓢ Specialist initiation only
- Ⓢ Specialist use only
- ? Awaiting final decision

Medicine name:	**Alteplase (Actilyse Cathflo®)** *Boehringer Ingelheim*	Indication:	**Thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.**
Reason for consideration:	**New formulation**	SMC decision:	**Accepted for restricted use within NHS Scotland (SMC 717/11) [Abbreviated]**
FND recommendation, restrictions on use and comments: **Deferred to allow further consultation with the renal and oncology service** **Interim non-Formulary status** The SMC restriction was for use where alteplase is the product of choice for the treatment of occluded venous access devices. This is a new formulation introduced for this extension to the alteplase marketing authorisation and the 2ml vial is the only presentation licensed for this indication.			**?**
ADTC decision 08/0811	AGREED		

Medicine name:	**Calcium Carbonate and Cholecalciferol (Kalcipos-D®)** *Meda Pharmaceuticals Ltd*	Indication:	**- Prevention and treatment of calcium and vitamin D deficiency in the elderly.** **- Vitamin D and calcium supplement in addition to specific osteoporosis treatment of patients who are at risk of vitamin D and calcium deficiency.**
Reason for consideration:	**New combination**	SMC decision:	**Accepted for use within NHS Scotland (SMC 718/11) [Abbreviated]**
FND recommendation, restrictions on use and comments: **Deferred to allow feedback from relevant specialists** **Interim non-Formulary status** This is a new combination product with a different ratio of calcium to cholecalciferol than alternative combination preparations. It is a similar price to an alternative product containing 800IU of cholecalciferol per tablet but is more expensive than some other calcium and cholecalciferol combinations. Any overall budget impact is likely to be small.			**?**
ADTC decision 08/08/11	AGREED		

Section 5: SMC advice that pertains to the GGC Paediatric Formulary

Medicine name:	**Methotrexate 50 mg/ml solution for injection (Metoject®)** *Medac GmbH*	Indication:	**Polyarthritic forms of severe active juvenile idiopathic arthritis, when the response to non-steroidal anti-inflammatory drugs has been inadequate.**
Reason for consideration:	**New presentation**	SMC decision:	**Accepted for use within NHS Scotland (SMC 724/11) [Abbreviated]**
FND recommendation, restrictions on use and comments: **Add to Paediatric Formulary** **Restricted to use under specialist supervision** For patients in whom treatment with disease modifying drugs is indicated and parenteral administration of methotrexate is appropriate, this adds to the range of pre filled syringes available. The Scottish Medicines Consortium has previously accepted methotrexate for the treatment of severe active rheumatoid arthritis in adult patients where treatment with disease modifying drugs is indicated. Methotrexate injection is listed in the British National Formulary for Children 2010 -11 for the treatment of juvenile idiopathic arthritis.			**✓R**
ADTC decision 08/08/11	AGREED		

Key to recommendations and symbols:

✓	Added to Formulary	Ⓢ	Specialist initiation only
✓R	Added to Formulary with restrictions	Ⓢ	Specialist use only
✗	Not added to Formulary	?	Awaiting final decision

Section 6: Other Formulary decisions – Appeals, reviews and NICE/SIGN guidance

Medicine name:	**Cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate**	Indication:	**Treatment of intermittent claudication in people with peripheral arterial disease.**
Reason for consideration:	**NICE MTA 223**	NHS HIS decision:	**Accepted for use within NHS Scotland (SMC 704/11)**

FND recommendation, restrictions on use and comments:

No change to the Formulary.

Naftidrofuryl oxalate is recommended as an option for the treatment of intermittent claudication in people with peripheral arterial disease for whom vasodilator therapy is considered appropriate after taking into account other treatment options. Treatment with naftidrofuryl oxalate should be started with the least costly licensed preparation.

Cilostazol, pentoxifylline and inositol nicotinate are not recommended for the treatment of intermittent claudication in people with peripheral arterial disease.

People currently receiving cilostazol, pentoxifylline and inositol nicotinate should have the option to continue treatment until they and their clinicians consider it appropriate to stop. This guidance replaces NICE technology appraisal guidance 111 issued in November 2006 (amended September 2007, August 2009).

ADTC decision 08/08/11	AGREED

Key to recommendations and symbols:

✓ Added to Formulary
✓R Added to Formulary with restrictions
✗ Not added to Formulary
S Specialist initiation only
S Specialist use only
? Awaiting final decision