Greater Glasgow and Clyde Area Drug and Therapeutics Committee
Formulary and New Drugs Sub-Committee

# NEW DRUG RECOMMENDATIONS
# MAY 2012

NHS Greater Glasgow and Clyde

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

| | | | |
|---|---|---|---|
| Medicine name: | Icatibant acetate (Firazyr®)<br>*Shire Human Genetic Therapies* | Reason for consideration: | New medicine |
| Indication under review: | Symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency). | | |
| SMC/ HIS reference: | SMC 476/08 [Resubmission] [Deferred Decision] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Icatibant treatment resulted in symptom relief in patients suffering acute abdominal, cutaneous and/or laryngeal attacks of hereditary angioedema.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of icatibant. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland. | | |
| FND recommendation: | Ⓢ Included on the Total Formulary for the indication in question restricted to use only on the advice of the Immunology Service.<br>Formulary status is contingent upon the availability of the PAS. | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

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

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| Medicine name: | Alteplase (Actilyse®)<br>*Boehringer Ingelheim* | Reason for consideration: | New indication |
| Indication under review: | The fibrinolytic treatment of acute ischaemic stroke. Treatment must be started as early as possible within 4.5 hours after onset of the stroke symptoms and after exclusion of intracranial haemorrhage by appropriate imaging techniques (e.g. cranial computerised tomography or other diagnostic imaging method sensitive for the presence of haemorrhage). | | |
| SMC/ HIS reference: | SMC 714/11 [Full Submission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Evidence for the extension of the time window in which alteplase can be administered is from a placebo-controlled study. Alteplase treatment resulted in significantly more patients having no symptoms or no significant disabling symptoms at three months compared to placebo. | | |
| FND recommendation: | Ⓢ Included on the Total Formulary for the indication in question restricted to specialist centres with adequate resources and appropriate expertise and in accordance with detailed protocols. | | ✓R |
| ADTC Decision 11/06/12 | 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: | Erlotinib (Tarceva®)<br>*Roche Products Ltd* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) activating mutations. | | |
| SMC/ HIS reference: | SMC 749/11 [Full Submission] [Deferred Decision] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | In patients with advanced or metastatic NSCLC with EGFR mutations, erlotinib was associated with significantly improved progression-free survival compared with platinum-based doublet chemotherapy regimens. There are no mature overall survival data.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of erlotinib. This SMC advice is contingent upon the continuing availability of the PAS in NHS Scotland. | | |
| FND recommendation: | Add to Total Formulary<br>Restricted to use in accordance with regional protocol. | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

| Medicine name: | Exenatide (Byetta®)<br>*Eli Lilly and Company Limited* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | As adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults with type 2 diabetes who have not achieved adequate glycaemic control with these agents. | | |
| SMC/ HIS reference: | SMC 785/12 [Full Submission] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | In the pivotal phase III study, addition of exenatide to basal insulin in combination with other anti-diabetic agents was associated with a clinically significant reduction in HbA1c of -0.7% compared with placebo, with 60% of patients achieving a target HbA1c level ≤7.0%. | | |
| FND recommendation: | Included on the Total Formulary for the indication in question. | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

| Medicine name: | Imatinib (Glivec®)<br>*Novartis Pharmaceuticals UK Ltd* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | Adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive gastrointestinal stromal tumours (GIST). Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. | | |
| SMC/ HIS reference: | SMC 584/09 [Resubmission] [Deferred Decision] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Restricted to use in patients at high risk of recurrence following complete resection (according to the Armed Forces Institute of Pathology (AFIP) risk criteria).<br><br>Imatinib, given for a period of one year, significantly improved the estimated one year recurrence-free survival compared with placebo and was associated with an increase of 16.4 months in median time to recurrence in patients at high risk of relapse following resection.<br><br>The economic case was demonstrated for a one-year adjuvant treatment duration only. | | |
| FND recommendation: | Add to Total Formulary<br>Restricted to use in accordance with regional protocol. | | ✓R |
| ADTC Decision 11/06/12 | 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

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|---|---|---|---|
| Medicine name: | Pregabalin oral solution (Lyrica®)<br>*Pfizer Ltd* | Reason for consideration: | New formulation |
| Indication under review: | For the treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalization and the treatment of Generalised Anxiety Disorder (GAD) in adults. | | |
| SMC/ HIS reference: | SMC 765/12 [Abbreviated Submission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | SMC restriction: pregabalin oral solution should be prescribed only for patients who find it difficult to or are unable to swallow tablets.<br><br>The following SMC restrictions to the use of pregabalin apply:<br>• Pregabalin is restricted to use in patients with peripheral neuropathic pain who have not achieved adequate pain relief from, or have not tolerated, conventional first and second line treatments for peripheral neuropathic pain. Treatment should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximally tolerated therapeutic dose.<br>• Pregabalin is restricted to use as adjunctive therapy in adults with partial seizures with or without secondary generalisation. It should be initiated only by physicians who have appropriate experience in the treatment of epilepsy and should be used principally in patients who have not benefited from treatment with an older anti-convulsant drug such as carbamazepine or sodium valproate, or for whom these drugs are unsuitable because of contra-indications, interaction or poor tolerance.<br><br>Pregabalin is not recommended for use in the treatment of Generalised Anxiety Disorder in adults as the company have not made a submission to SMC for use in this indication.<br><br>Pregabalin oral solution has been shown to be bioequivalent to pregabalin capsules. | | |
| FND recommendation: | Included on the Total Formulary for the indication in question restricted to use in accordance with current SMC and Formulary advice for pregabalin.<br><br>Additional restriction for this formulation: Only in patients who find it difficult to or are unable to swallow tablets. | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

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|---|---|---|---|
| Medicine name: | Tobramycin (TOBI Podhaler®)<br>*Novartis Pharmaceuticals UK Limited* | Reason for consideration: | New formulation |
| Indication under review: | Suppressive therapy of chronic pulmonary infection due to *Pseudomonas aeruginosa* in adults and children aged 6 years and older with cystic fibrosis. Consideration should be given to official guidance on the appropriate use of antibacterial agents. | | |
| SMC/ HIS reference: | SMC 783/12 [Full Submission] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Tobramycin inhalation powder (TOBI Podhaler®) has demonstrated non-inferiority to tobramycin inhalation solution (via a nebuliser) measured by relative change in $FEV_1$ % predicted over three treatment cycles in a phase III, open-label, randomised study.<br><br>This preparation offers an alternative to nebulised tobramycin. The company did not make a case for cost-effectiveness relative to other nebulised antimicrobials.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tobramycin inhalation powder (TOBI Podhaler®). This SMC advice is contingent upon the continuing availability of the patient access scheme in Scotland. | | |
| FND recommendation: | Ⓢ Included on the Total Formulary for the indication in question.<br>Restricted to second-line use after colistimethate (colistin).<br>Formulary status is contingent upon the availability of the PAS.<br><br>NB: Formulary inclusion relates to all available brands of nebulised tobramycin, but prescribers are asked to use the preparation with the lowest acquisition cost taking account of patient tolerability. | | ✓R |
| ADTC Decision 11/06/12 | 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 3: Medicines accepted by SMC – Not included in Formulary

No entries in this section

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

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| Medicine name: | Collagenase clostridium histolyticum (Xiapex®)<br>*Pfizer Ltd* | Reason for consideration: | New medicine |
| Indication under review: | Treatment of Dupuytren's contracture in adult patients with a palpable cord. | | |
| SMC/ HIS reference: | SMC 715/11 [Resubmission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | SMC restriction: restricted to use as an alternative to limited fasciectomy in adult patients with Dupuytren's contracture of moderate severity (as defined by the British Society for Surgery of the Hand (BSSH), with a palpable cord and up to two affected joints per hand, who are suitable for limited fasciectomy, but for whom percutaneous needle fasciotomy is not considered a suitable treatment option.<br><br>Collagenase clostridium histolyticum compared to placebo significantly reduces primary joint contracture in adults with Dupuytren's contracture and palpable cord.<br><br>The cost-effectiveness of collagenase clostridium histolyticum relative to percutaneous needle fasciotomy was not demonstrated. | | |
| FND recommendation: | Not included in the GGC Adult Formulary pending protocol<br>(Clinical Lead for Orthopaedics) | | ✘ |
| ADTC Decision 11/06/12 | AGREED | | |

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|---|---|---|---|
| Medicine name: | Dexmedetomidine (Dexdor®)<br>*Orion Pharma UK* | Reason for consideration: | New medicine |
| Indication under review: | For sedation in adult intensive care unit (ICU) patients requiring a sedation level not deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale [RASS] 0 to -3). | | |
| SMC/ HIS reference: | SMC 784/12 [Full Submission] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Dexmedetomidine was as effective as propofol and midazolam in maintaining the target depth of sedation in ICU patients. The median duration of mechanical ventilation was numerically shorter with dexmedetomidine than with propofol and significantly shorter than with midazolam. | | |
| FND recommendation: | Not included in the GGC Adult Formulary pending protocol<br>(Critical Care Group / Clinical Lead for Anaesthetics). | | ✘ |
| ADTC Decision 11/06/12 | 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: | Dexamethasone (Ozurdex®)<br>*Allergan Ltd* | Reason for consideration: | New medicine |
|---|---|---|---|
| Indication under review: | Treatment of adult patients with macular oedema following either branch retinal vein occlusion or central retinal vein occlusion. | | |
| SMC/ HIS reference: | SMC 652/10 [Resubmission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | SMC restriction: for use in adult patients with macular oedema (i) following central retinal vein occlusion (CRVO) and (ii) in patients with branch retinal vein occlusion (BRVO) who are not clinically suitable for laser treatment including patients with dense macular haemorrhage or patients who have received and failed on previous laser treatment.<br><br>In two phase III studies dexamethasone 700 microgram intravitreal implant was superior to sham administration at day 90 for the proportion of patients with a best corrected visual acuity improvement of ≥15 letters. Longer-term effectiveness of treatment is uncertain. | | |
| FND recommendation: | Not included in the GGC Adult Formulary pending protocol (Clinical Lead for Ophthalmology). | | ✘ |
| ADTC Decision 11/06/12 | AGREED | | |

| Medicine name: | Everolimus (Afinitor®)<br>*Novartis Pharmaceuticals UK Limited* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | Treatment of unresectable or metastatic, well or moderately-differentiated neuroendocrine tumours of pancreatic origin (pNET) in adults with progressive disease. | | |
| SMC/ HIS reference: | SMC 777/12 [Full Submission] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Everolimus was superior to placebo in prolonging progression-free survival in adults with progressive, advanced pNET who were receiving best supportive care. | | |
| Financial Impact: | DAD indicates small budget impact but may be offered to a wider population than sunitinib and provision in 2012/13 plan (£126k). | | |
| Governance issues: | | | |
| FND recommendation: | Not included in the GGC Adult Formulary for the indication in question pending protocol (Regional Cancer Advisory Group). | | ✘ |
| ADTC Decision 11/06/12 | AGREED | | |

## Section 5: Medicines not recommended by SMC

| Medicine name: | Belatacept (Nulojix®)<br>*Bristol Myers Squibb Pharmaceuticals Ltd* | Reason for consideration: | New medicine |
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| Indication under review: | Belatacept, in combination with corticosteroids and a mycophenolic acid, is indicated for prophylaxis of graft rejection in adults receiving a renal transplant. It is recommended to add an interleukin-2 receptor antagonist for induction therapy to this belatacept-based regimen. | | |
| SMC/ HIS reference: | SMC 786/12 [Full Submission] | | |
| Summary of advice: | Not recommended for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Results of two phase III studies have demonstrated comparable graft and patient survival of belatacept versus a calcineurin inhibitor when used as part of a maintenance immunosuppressive regimen. Indirect efficacy data from a mixed treatment comparison are available for belatacept versus another calcineurin inhibitor, considered the key comparator in NHS Scotland.<br><br>The submitting company's justification for the treatment's cost in relation to its health benefits was not sufficient and in addition, the company did not present a sufficiently robust economic case to gain acceptance by SMC. | | |
| FND recommendation: | Not included in the GGC Adult Formulary. | | ✘ |

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

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|---|---|---|---|
| Medicine name: | Bevacizumab (Avastin®)<br>*Roche Products Ltd* | Reason for consideration: | New indication |
| Indication under review: | Bevacizumab in combination with capecitabine is indicated for first-line treatment of patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. | | |
| SMC/ HIS reference: | SMC 778/12 [Full Submission] | | |
| Summary of advice: | Not recommended for use within NHS Scotland | | |
| SMC/HIS restriction and comments: | In a double-blind, multicentre, randomised, placebo-controlled phase III study in patients with locally recurrent or metastatic breast cancer, treatment with bevacizumab plus capecitabine was associated with an extended median progression-free survival of 2.9 months compared with capecitabine monotherapy. However, there was no overall significant improvement in survival.<br><br>The submitting company did not present a sufficiently robust economic analysis and, in addition, their justification of the treatment's cost in relation to its health benefits was not sufficient to gain acceptance by the SMC. | | |
| FND recommendation: | Not included in the GGC Adult Formulary for the indication in question. | | ✘ |

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|---|---|---|---|
| Medicine name: | Ipilimumab (Yervoy®)<br>*Bristol-Myers Squibb* | Reason for consideration: | New medicine |
| Indication under review: | Treatment of advanced (unresectable or metastatic) melanoma in adults who have received prior therapy. | | |
| SMC/ HIS reference: | SMC 779/12 [Full Submission] | | |
| Summary of advice: | Not recommended for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Ipilimumab demonstrated a survival benefit over an investigational gp100 peptide vaccine in previously treated patients with advanced melanoma.<br><br>The submitting company's justification of the treatment's cost in relation to its health benefits was not sufficient and, in addition, 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. | | ✘ |

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| Medicine name: | Triptorelin (Salvacyl®)<br>*Ipsen Ltd* | Reason for consideration: | New indication |
| Indication under review: | Reversible reduction of testosterone to castrate levels in order to decrease sexual drive in adult men with severe sexual deviations. | | |
| SMC/ HIS reference: | SMC 796/12 [Non Submission] | | |
| Summary of advice: | Not recommended for use in 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 NHS Scotland. | | |
| FND recommendation: | Not included in the GGC Adult Formulary for the indication in question. | | ✘ |

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|---|---|---|---|
| Medicine name: | Vandetanib (Caprelsa®)<br>*AstraZeneca UK Limited* | Reason for consideration: | New medicine |
| Indication under review: | Treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. | | |
| SMC/ HIS reference: | SMC 797/12 [Non Submission] | | |
| Summary of advice: | Not recommended for use in 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 NHS Scotland. | | |
| FND recommendation: | Not included in the Adult GGC Formulary. | | ✘ |

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

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|---|---|---|---|
| Medicine name: | Abatacept (Orencia®)<br>*Bristol-Myers Squibb Pharmaceuticals Ltd* | Reason for consideration: | New indication |
| Indication under review: | In combination with methotrexate, abatacept is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other disease modifying antirheumatic drugs (DMARDs) including at least one tumour necrosis factor (TNF) inhibitor. It has not been studied in children under 6 years old. | | |
| SMC/ HIS reference: | SMC 618/10 [Abbreviated Submission] [Deferred Decision] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Abatacept is an anti-rheumatic agent that prevents T-lymphocyte activation.<br><br>Abatacept in combination with methotrexate has been accepted for restricted use in adults with severe active rheumatoid arthritis in line with the recommendations of the NICE Multiple Technology Appraisal no 195. NHS Quality Improvement Scotland advised that these recommendations were valid for NHS Scotland. | | |
| FND recommendation: | Included on the GGC Paediatric Formulary for the indication in question restricted to use within paediatric rheumatology.<br>No change required for GGC Adult Formulary. | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

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|---|---|---|---|
| Medicine name: | Adalimumab (Humira®)<br>*Abbott Laboratories* | Reason for consideration: | New indication |
| Indication under review: | In combination with methotrexate for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Adalimumab can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in children aged less than 4 years. | | |
| SMC/ HIS reference: | SMC 738/11 [Abbreviated Submission] [Deferred Decision] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | It should be restricted to use within specialist rheumatology services (including those working within the network for paediatric rheumatology). Combination treatment with methotrexate is the primary option. Doses in this age group are based on body surface area calculations.<br><br>The Scottish Medicines Consortium has previously accepted this product for restricted use for this indication in adolescents aged 13 to 17 years and for rheumatoid arthritis in adults. | | |
| FND recommendation: | Included on the GGC Paediatric Formulary for the indication in question restricted to use within paediatric rheumatology.<br>No change required for GGC Adult Formulary. | | ✓R |
| ADTC Decision 11/06/12 | 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

| Medicine name: | Etanercept (Enbrel®)<br>*Pfizer* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | For the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. | | |
| SMC/ HIS reference: | SMC 781/12 [Abbreviated Submission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | SMC restriction:<br>- 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;<br>- the psoriasis has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments;<br>- etanercept treatment should be discontinued in patients whose psoriasis has not responded adequately at 12 weeks.<br><br>Etanercept has previously been accepted for use in this indication in adults in NHS Scotland as NHS Health Improvement Scotland advised that NICE Multiple Technology Appraisal No 103 is valid for Scotland. Etanercept has previously been accepted for restricted use by SMC in adolescents and children from the age of 8 years.<br><br>Etanercept is also listed in the British National Formulary for Children 2011-2012 as one of a number of drugs affecting the immune response available for treatment of severe refractory psoriasis. | | |
| FND recommendation: | Not included in the Paediatric Formulary pending further consultation.<br>No change required for GGC Adult Formulary. | | ✘ |
| ADTC Decision 11/06/12 | AGREED | | |

| Medicine name: | Etanercept (Enbrel®)<br>*Pfizer* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | For the treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. | | |
| SMC/ HIS reference: | SMC 782/12 [Abbreviated Submission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | SMC restriction: use within specialist rheumatology services (including those working within the network for paediatric rheumatology).<br><br>Etanercept has previously been accepted for use for this indication in children and adolescents from the age of 4-17 years in NHS Scotland as NHS Health Improvement Scotland advised that NICE Multiple Technology Appraisal No 35 is valid for Scotland.<br><br>Etanercept is also listed in the British National Formulary for Children 2011-2012 as one of a number of treatment options for juvenile idiopathic arthritis. | | |
| FND recommendation: | Included on the GGC Paediatric Formulary for the indication in question restricted to use within paediatric rheumatology.<br>No change required for GGC Adult Formulary. | | ✓R |
| ADTC Decision 11/06/12 | 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

| Medicine name: | Insulin detemir (Levemir®)<br>*NovoNordisk* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. | | |
| SMC/ HIS reference: | SMC 780/12 [Abbreviated Submission] | | |
| Summary of advice: | Accepted for restricted use in NHS Scotland | | |
| SMC/HIS restriction and comments: | SMC restriction: in patients unable to achieve good glycaemic control with established insulins.<br><br>Insulin detemir has previously been accepted for restricted use by SMC in adults, adolescents and children from 6 years of age. Insulin detemir is included in the British National Formulary for Children 2011-2012. | | |
| FND recommendation: | Included on the GGC Paediatric Formulary for the indication in question restricted to use in patients unable to achieve good glycaemic control with established insulins.<br>No change required for GGC Adult Formulary. | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

| Medicine name: | Tocilizumab (RoActemra®)<br>*Roche Products Limited* | Reason for consideration: | New indication |
|---|---|---|---|
| Indication under review: | Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given as monotherapy (in case of intolerance to methotrexate or where treatment with methotrexate is inappropriate) or in combination with methotrexate. | | |
| SMC/ HIS reference: | SMC 754/12 [Full Submission] [Deferred Decision] | | |
| Summary of advice: | Accepted for use in NHS Scotland | | |
| SMC/HIS restriction and comments: | Tocilizumab was superior to placebo in reducing disease activity and fever in patients with persistent active systemic juvenile idiopathic arthritis despite treatment with NSAIDs and corticosteroids.<br><br>This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of tocilizumab. This SMC advice is contingent upon the continuing availability of the Patient Access Scheme in NHS Scotland. | | |
| FND recommendation: | Included on the GGC Paediatric Formulary for the indication in question restricted to use within paediatric rheumatology.<br>Formulary status is contingent upon the availability of the PAS.<br>No change required for GGC Adult Formulary | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

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

| Medicine name: | Bee or wasp venom immunotherapy (Pharmalgen®)<br>*ALK-Abello* | Indication: | Treatment of IgE-mediated bee and wasp venom allergy in people with severe systemic reaction to bee or wasp venom |
|---|---|---|---|
| Reason for consideration: | NICE MTA246 | SMC decision: | N/A |
| FND recommendation, restrictions on use and comments:<br>Ⓢ Included in the Total Formulary for the indication in question restricted to use only at the specialist centres by appropriate specialists. | | | ✓R |
| ADTC Decision 11/06/12 | 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

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|---|---|---|---|
| Medicine name: | Cetuximab, bevacizumab and panitumumab | Indication: | For the treatment of metastatic colorectal cancer after first-line chemotherapy *(partial update of previous guidance to review Imatinib resistance/intolerance)* |
| Reason for consideration: | NICE MTA242 | SMC decision: | Not recommended for all three medicines. |
| FND recommendation, restrictions on use and comments:<br>Acknowledge new guidance.<br>No change to Formulary status required. | | | ✘ |
| ADTC Decision 11/06/12 | AGREED | | |

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|---|---|---|---|
| Medicine name: | Dasatinib, nilotinib and standard-dose imatinib | Indication: | For the first-line treatment of chronic myeloid leukaemia (part review of technology appraisal guidance 70) |
| Reason for consideration: | NICE MTA251 | SMC decision: | |
| FND recommendation, restrictions on use and comments:<br>Decision deferred for consultation with the Regional Cancer Advisory Group. | | | ✘ |
| ADTC Decision 11/06/12 | AGREED | | |

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| Medicine name: | Macrogol (Laxido Orange®)<br>*Galen Ltd* | Indication: | Treatment of constipation requiring an osmotic laxative. |
| Reason for consideration: | Formulary Appeal | SMC decision: | Not applicable |
| FND recommendation, restrictions on use and comments:<br>Appeal not upheld.<br>Promotion of Laxido Orange® as first choice macrogol preparation via Prescribing Indicators in primary care is already proving successful. Inclusion of Laxido Orange® in the GGC e-Formularies for GP Prescribing Systems was discussed as an additional useful step which FND are supportive of; however, a change to Formulary positioning is not mandatory in order to progress this. | | | ✓R |
| ADTC Decision 11/06/12 | AGREED | | |

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|---|---|---|---|
| Medicine name: | Oxycodone MR tablets (OxyContin®)<br>*Napp* | Indication: | Post-operative analgesia following uterine artery embolisation (UAE) in adults. |
| Reason for consideration: | Formulary Appeal | SMC decision: | Accepted for restricted use in NHS Scotland (SMC 197/05) |
| FND recommendation, restrictions on use and comments:<br>Appeal not upheld.<br>Proposed use of oxycodone goes against SMC restrictions on use and sufficient benefit over existing Formulary alternatives was not demonstrated. | | | ✘ |
| ADTC Decision 11/06/12 | 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