



## Tayside ADTC Supplement No 157 – November 2016

Produced by NHS Tayside Drug and Therapeutics Committee Medicines Advisory Group (MAG)

### Special Points of Interest for Primary Care

#### SMC Advice - September:

- Bevacizumab (Avastin®)
- Calcipotriol (Enstilar®)
- Carfilzomib (Kyprolis®)
- Cobimetinib (Cotellic®)
- Dasatinib (Sprycel®)
- Fosfomycin trometamol Monuril®)
- Idarucizumab (Praxbind®)
- Iron (III) isomaltoside (Diafer®)
- Liraglutide (Victoza®)
- Paliperidone pamate (Trevicta®)
- Trametinib (Mekinist®)



## Drug Safety Updates

Please follow link - Drug Safety Update Download - [September 2016](#) | [October 2016](#)



## Guidelines and Protocols

### Phenytoin Prescribing and Monitoring Guideline

A [guideline](#) for the prescribing and monitoring of the antiepileptic agent phenytoin has been published. It has been reviewed by the NHS Tayside Neurology Clinical Governance Group and the NHS Tayside Medicines Advisory Group.

The guidance includes advice on the intravenous loading dose for phenytoin in status epilepticus, top up dose for patients in status epilepticus who are already taking phenytoin, guidance on maintenance phenytoin therapy and therapeutic drug monitoring.

There is also information within the guidance on phenytoin administration via enteral feeding tubes, the correction of phenytoin levels in hypoalbuminaemia and renal failure, and on signifi-

The guideline has been linked to the oral and IV entries for phenytoin within the formulary, the [Epilepsy Specialist formulary list](#), and included in the News Feed on the formulary homepage.

## Tayside Medicine for the Elderly Osteoporosis Treatment Algorithm

The [Medicine for the Elderly \(MFE\) Osteoporosis treatment algorithm](#) (Staffnet intranet link) has recently been reviewed and updated.

It has been updated to reflect:

- SIGN Guideline No. 142 - [Management of osteoporosis and the prevention of fragility fractures, March 2015](#)
- MHRA guidance on [strontium ranelate and cardiovascular risk, March 2014](#)
- Available information on fracture healing and treatment of osteoporosis
- [NHS Tayside Guidance on Management of Vitamin D deficiency in Adults, April 2013](#) (Staffnet intranet link)
- [Guidelines for the management of chronic kidney disease mineral and bone disorder, September 2016](#) (Staffnet intranet link)

Links to the MFE Osteoporosis treatment algorithm within the formulary and on Staffnet have been replaced with the updated version.

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This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Area Drug and Therapeutics Committee (ADTC).

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# Guidelines and Protocols

## Mepolizumab and Omalizumab Local Treatment Protocols

Mepolizumab is a recently approved monoclonal antibody that inhibits binding of interleukin-5 (IL-5) to the IL-5 receptor expressed on the surface of eosinophils and its inhibition reduces production and survival of eosinophils. Mepolizumab has been accepted for restricted use within NHS Scotland. It is for prescribing by Consultant Respiratory Physicians only, as an add-on treatment for severe refractory eosinophilic asthma in adult patients.

A [local treatment protocol for mepolizumab for adults](#) (Staffnet intranet link) has been produced by the NHS Tayside Respiratory MCN. They have also reviewed the [omalizumab local treatment protocol for adults and adolescents \(12 years+\)](#) (Staffnet intranet link), and produced an [algorithm for assessment of response to monoclonal antibody treatment for severe asthma in NHS Tayside](#) (Staffnet intranet link). The algorithm includes information on eligibility criteria, patient assessment and review for both mepolizumab and omalizumab.

The local treatment protocols and algorithm have been linked to the entries for mepolizumab and omalizumab within the formulary and [Respiratory Specialist formulary list](#).



## Prescribing Changes

### Oral Nutritional Supplements (ONS) in Adults

Advice for Prescribing Oral Nutritional Supplements (ONS) in Adults.

To improve ONS prescribing practices and help ensure appropriate use in the community setting, an NHS Tayside 'GP, Community Nurse and Specialist Nurse Oral Nutritional Supplement (ONS) Formulary for Adults' has been developed. The new formulary:

- Promotes Aymes Shake and Complan Shake oral ONS powders as the first line option for undernourished patients. All new ADULT patients requiring ONS should be prescribed a product from the ONS formulary.
- Gives timescales for length of time for ONS prescription and when to refer to a dietitian
- Provides information for prescribers to check that their patient meets the Standard Advisory Committee of Borderline Substances (ACBS) criteria for ONS prescriptions.
- Includes guidance specifically requested by GPs for drug and/or alcohol misuse and palliative care.
- Encourages an ALWAYS use 'Food First' approach before considering prescribing ONS.
- Advises that some patients may have to change to a different ONS product on discharge from hospital as Aymes Shake and Aymes Complete are only available in the community.

#### Tayside Nutrition MCN Website

Resources for clinicians, patients and carers are available on the Tayside Nutrition MCN website including 'Food First' suggestions: [http://www.knowledge.scot.nhs.uk/taysidenutrition/oral-nutritional-support-\(ons\).aspx](http://www.knowledge.scot.nhs.uk/taysidenutrition/oral-nutritional-support-(ons).aspx)

A link to the Tayside Oral Nutritional Supplements (ONS) Formulary for Adults has been added to the Tayside Area Formulary homepage.

Please feel free to share this information with colleagues.

For further information please contact the Lead ONS dietitians:

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Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®)  SMC 1190/16 Absence of submission Not recommended	In combination with erlotinib for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations.	Not available as not recommended for use in NHS Scotland.	<a href="#">SMC Link</a>
Calcipotriol 50micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®)  SMC 1182/16 Abbreviated submission Accepted	Topical treatment of psoriasis vulgaris in adults.	Available in line with National Guidance  Formulary Green traffic light	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Carfilzomib 60mg powder for solution for infusion (Kyprolis®)  SMC 1171/16 Full submission under orphan medicines process Not recommended	In combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy	Not available as not recommended for use in NHS Scotland.	<a href="#">SMC Link</a>
Cobimetinib 20mg film-coated tablets (Cotellic®)  SMC 1191/16 Absence of submission Not recommended	In combination with vemurafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.	Not available as not recommended for use in NHS Scotland.	<a href="#">SMC Link</a>
Dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®)  SMC 1170/16 Full submission under orphan process Accepted	For the treatment of adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukaemia (CML) in the chronic phase.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Dasatinib 20mg, 50mg, 80mg, 100mg and 140mg film-coated tablets (Sprycel®)  SMC 371/07 Re-submission under orphan process Accepted	For the treatment of adult patients with chronic, accelerated or blast phase chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Fosfomycin trometamol granules for oral solution (equivalent to 3g fosfomycin) (Monuril®)  SMC 1163/16 Abbreviated submission Accepted	Treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females. Prophylaxis in diagnostic and surgical transurethral procedures. Consideration should be given to national guidance on the appropriate use of antibacterial agents.	Available in line with local prescribing guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Idarucizumab 2.5g/50ml solution for injection/infusion (Praxbind®)  SMC 1178/16 Full submission Accepted	Idarucizumab is a specific reversal agent for dabigatran and is indicated in adult patients treated with dabigatran etexilate when rapid reversal of its anticoagulant effects is required for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding.	Available in line with National Guidance  Hospital Use Only	<a href="#">SMC Link</a> <a href="#">SPC Link</a>

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#).

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Iron (III) isomaltoside 1000 (contains 50mg iron per ml) solution for injection (Diafer®)  SMC 1177/16 Full submission Not recommended	For the treatment of iron deficiency in adults with chronic kidney disease (CKD) on dialysis, when oral iron preparations are ineffective or cannot be used.	Not available as not recommended for use in NHS Scotland.	<a href="#">SMC Link</a>
Liraglutide 6mg/ml solution for injection in pre-filled pen (Victoza®)  SMC 1192/16 Absence of submission Not recommended	As monotherapy for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control when diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance or contra-indications.	Not available as not recommended for use in NHS Scotland.	<a href="#">SMC Link</a>
Paliperidone palmitate 175mg, 263mg, 350mg, 525mg prolonged release suspension for injection (Trevicta®)  SMC 1181/16 Abbreviated submission Accepted	A three-monthly injection, indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on one-monthly paliperidone palmitate injectable product.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Trametinib 0.5mg and 2mg film-coated tablets (Mekinist®)  SMC 1161/16 Full submission under end of life and ultra-orphan medicine process Accepted restricted	In combination with dabrafenib for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.  <b>SMC Restriction:</b> first-line treatment.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	<a href="#">SMC Link</a> <a href="#">SPC Link</a>

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Updates from previous SMC Advice			
Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Abiraterone (Zytiga®) SMC 873/13	Abiraterone acetate is indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Bevacizumab (Avastin®) SMC 1063/15	In combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other vascular endothelial growth factor (VEGF) inhibitors or VEGF receptor-targeted agents.  <b>SMC Restriction:</b> to use in combination with paclitaxel.	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>

## Updates from previous SMC Advice

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Brivaracetam (Briviact) SMC 1160/16	Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.  <b>SMC Restriction</b> for use in patients with refractory epilepsy and treatment, should be initiated by physicians who have appropriate experience in the treatment of epilepsy.	Available in line with National Guidance	<a href="#">SMC Link</a> SPC Links: <a href="#">Oral Solution</a> <a href="#">Solution for Injection/Infusion</a> <a href="#">Film-coated tablets</a>
Ceritinib (Zykadia®) SMC 1097/15	Treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Diamorphine hydrochloride (Ayendi) SMC 1172/16	Treatment of acute severe nociceptive pain in children and adolescents in a hospital setting. Diamorphine hydrochloride nasal spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children with appropriate monitoring.	Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time or there is a local preference for alternative medicines	<a href="#">SMC Link</a>
Guanfacine (Intuniv®) SMC 1123/16	Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated, or have been shown to be ineffective.	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Idelalisib (Zydelig®) SMC 1039/15	Monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.	Available in line with National Guidance	<a href="#">SMC Link</a> SPC Links: <a href="#">100mg</a> <a href="#">150mg</a>
Lenalidomide (Revlimid®) SMC 1096/15	Treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.  <b>SMC Restriction:</b> for use in patients unsuitable for thalidomide-containing regimens.	Available in line with National Guidance	<a href="#">SMC Link</a> SPC Links: <a href="#">2.5mg</a> <a href="#">5mg</a> <a href="#">7.5mg</a> <a href="#">10mg</a> <a href="#">15mg</a> <a href="#">20mg</a> <a href="#">25mg</a>
Mepolizumab (Nucala®) SMC 1149/16	As an add on treatment for severe refractory eosinophilic asthma in adult patients.  <b>SMC Restriction:</b> patients who have had eosinophils of at least 150cells per microlitre at initiation of treatment and have had at least four asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids.	Available in line with local guidance for prescribing	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Netupitant/palonoestron (Akynzeo®) SMC 1109/15	In adults for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy and moderately emetogenic cancer chemotherapy.  <b>SMC restriction:</b> prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based cancer chemotherapy.	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Nintedanib (Vargatef®) SMC 1027/15	In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>
Pembrolizumab (Keytruda®) SMC 1086/15	As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults. This submission relates to use in adults previously untreated with ipilimumab.	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>

## Updates from previous SMC Advice

Medicine	Condition Being Treated	NHS Board Decision	Comments and Useful Links
Trastuzumab (Herceptin®) SMC 623/10	In combination with capecitabine or fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-oesophageal junction who have not received prior anti-cancer treatment for their metastatic disease. It is indicated for use only in patients with metastatic gastric cancer whose tumours have HER2 over-expression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.  <b>SMC restriction:</b> for use in patients whose tumours have HER2 overexpression defined by immunohistochemistry (IHC) 3+ ("HER2 high expresser").	Available in line with National Guidance	<a href="#">SMC Link</a> <a href="#">SPC Link</a>

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[CLICK HERE](#) for access to the Medicines Governance section of the Pharmacy Staffnet site.



## Tayside Area Formulary (TAF) Updates - October 2016

Medicines within the Tayside Area Formulary are intended to guide choice on a rational selection of medicines for **adults** which have been included on the basis of clinical efficacy, safety, patient acceptability and cost-effectiveness.

TAF Section	Drug(s)/topic	Changes
<a href="#">02.08.01</a>	Low molecular weight heparins	Statement and advice added on dosing in extremes of body weight for dalteparin thromboprophylaxis. Link to Tayside document <a href="#">Monitoring of Low Molecular Weight Heparin</a> (external link) added.
<a href="#">02.08.02</a>	Oral anticoagulants	Idarucizumab solution for injection/infusion (Praxbind®▼) added as non-formulary. Note added that it is available only on advice from haematology (for Hospital use) as a reversal agent when the rapid reversal of dabigatran is clinically necessary. See SMC advice on page 3.
<a href="#">03.04.02</a>	Allergen Immunotherapy	Mepolizumab powder for solution for injection (Nucala®▼) added to formulary and <a href="#">Respiratory Specialist Formulary list</a> as Hospital Only (Red traffic light) - restricted to prescribing by Consultant Respiratory Physicians as an add-on treatment for severe refractory eosinophilic asthma in adult patients. Link to <a href="#">mepolizumab local protocol</a> and <a href="#">algorithm for assessment of response to monoclonal antibody treatment for severe asthma</a> added (Staffnet intranet links). Updated <a href="#">local protocol for omalizumab</a> (Staffnet intranet link) added along with link to algorithm.
<a href="#">04.02.02</a>	Antipsychotic depot injections	Paliperidone palmitate prolonged release suspension for injection (Trevicta®) added as non-formulary. Note added not to confuse with monthly paliperidone palmitate depot injection (Xeplion®).
<a href="#">04.08.01</a>	Control of epilepsy	Brivaracetam film coated tablets, oral solution, solution for injection/infusion added to formulary and <a href="#">Epilepsy Specialist Formulary list</a> as second-line adjunctive treatment of focal epilepsy in patients from 16 years of age who have been refractory to treatment. GPs may prescribe under specialist direction (Amber traffic light). Link to <a href="#">Phenytoin Prescribing and Monitoring Guideline</a> added to phenytoin oral and IV formulary entries, and the <a href="#">Epilepsy Specialist Formulary list</a> .
<a href="#">06.01.02.04</a>	DPP-4 inhibitors	Note on avoiding DPP-4 inhibitors in moderate or severe heart failure re-worded to use with caution due to limited experience with use.
<a href="#">06.06</a>	Drugs affecting bone metabolism	Links to <a href="#">Tayside MFE Osteoporosis Treatment Algorithm</a> (Staffnet intranet link) are now to the updated version.
<a href="#">13.05.02</a>	Vitamin D and analogues	Calcipotriol 50micrograms/g and betamethasone 0.5g/g cutaneous foam (Enstilar®) added to formulary (Green traffic light) restricted to patients who are unable to comply with an alternating regimen of topical vitamin D analogue in the morning and topical steroid at night or alternate days vitamin D analogue and topical steroid as per other formulations available e.g. gel, ointment.

### [SMC Monthly Briefing Notes 2016](#)

### [Forthcoming SMC Advice](#)

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