



Tayside DTC Supplement No. 149 – June/July 2015

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

Special Points of Interest for Primary Care

- High Dose Betahistine Treatment Protocol
- UKMi Medicines Compliance Aid Database

SMC Advice - June:

- Apremilast (Otezla®)
- Cangrelor (Kengravel®)
- Levonorgestrel (Levosert®)
- Linagliptin (Jentaducto®)
- Ombitasvir/paritaprevir/ritonavir (Viekirax®) and dasabuvir (Exviera®)
- Paclitaxel albumin (Abraxane®)
- Secukinumab (Cosentyx®)

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Specialist Lists

General Surgery

The [General Surgery Specialist Formulary List](#) has been finalised. This includes specialist medicines which are prescribed within Colorectal, Upper GI, or Vascular Surgery.

Medicines included are classed as Hospital Only (Red traffic light) or for prescribing by GPs under the direction of a Consultant Surgeon (Amber traffic light).

The list can be accessed from the formulary home page by clicking on Specialist Formulary

Substance Misuse

The [Substance Misuse Specialist Formulary List](#) has been developed along with the recent formulary updates for Substance Misuse which have been made in line with the [NICE Pathway, Drug Misuse, April 2014](#) and the [NICE Pathway, Alcohol-use disorders, June 2014](#).



Drug Safety Updates

Please follow link - [Drug Safety Update Download - June 2015](#)



Guidelines and Protocols

High Dose Betahistine Local Treatment Protocol

A local treatment protocol for the use of high dose betahistine in Ménière's disease has been developed.

The protocol covers the 'off-label' use of betahistine in the following circumstance:

Higher than licensed dosage (48mg three times daily for up to 12 months) for licensed indications (Vertigo, tinnitus and hearing loss associated with Ménière's disease) in patients not responding to standard dose treatment (16mg three times daily, for a minimum of 6 months) who do not have adverse effects at standard dosage. After betahistine high dose treatment [off-label] for up to 12 months (ideally 6 months) the dose is reduced to a licensed dose of 16mg three times daily.

Local recommendation

GPs may prescribe under the direction of a specialist ENT surgeon.

Monitoring - response to treatment and treatment safety

Regular follow up with specialist ENT surgeon (3 monthly or sooner if problems).

[CLICK HERE](#) for the local treatment protocol.



UKMi Medicines Compliance Aid Database

The [UKMi Medicines Compliance Aid Database](#) is now available from the home page of the Knowledge Network.

A Medicine Compliance Aid Database has been available via the UK Medicines Information (UKMi) website since 2014 (DTC supplement 143). It is aimed at health care professionals, for example community pharmacists, who may require knowledge on whether a medicine will be stable in a medicine compliance aid (MCA). In line with Royal Pharmaceutical Society guidance the use of original packs is the preferred option. However, in certain situations medicines compliance aids are used to allow patients to take their medicines appropriately.

To access the Medicine Compliance Aid database go to the home page of [The Knowledge Network \(TKN\)](#).

Click on Medicine Information Resources (3rd bullet point under 'What is here for Me' - half way down the home page on the right hand side) . Click on UK Medicines Compliance Aid database and click on 'Notes read confirmation box' at the bottom to proceed to the database.

SMC Advice issued in May 2015 (publication date 8 June 2015)

SMC website: www.scottishmedicines.org.uk

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
apremilast (Otezla®) SMC No. 1052/15 Full submission	For the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA).	Hospital Only Dermatology Clinic Dermatology Specialist List	SMC advice SPC link (10mg, 20mg and 30mg film-coated tablets) CLICK HERE for the Local Treatment Protocol
apremilast (Otezla®) SMC No. 1053/15 Full submission	For use alone or in combination with disease modifying anti-rheumatic drugs (DMARDs), for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. SMC restriction: for use in adult patients with active PsA who have had an inadequate response with at least two prior DMARD therapies or who are intolerant to such therapies.	Non Formulary Pending local agreement	SMC advice
cangrelor (Kengrexel®) SMC No. 1070/15 No submission	Co-administered with acetylsalicylic acid for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable.	Not recommended	SMC advice
levonorgestrel (Levosert®) 20 micro-grams/24 hours intrauterine delivery system SMC No. 1058/15 Abbreviated submission	Contraception. Heavy menstrual bleeding.	Non Formulary Absence of clinician demand	SMC advice

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Medicine	Indication	Local Recommendation Category	Comments and Useful Links
linagliptin plus metformin (Jentaduo [®]) SMC No. 1057/15 Abbreviated submission	For the treatment of adult patients with type 2 diabetes mellitus in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control when insulin and metformin alone do not provide adequate glycaemic control.	Non Formulary Absence of clinician demand	SMC advice
ombitasvir/paritaprevir/ritonavir (Viekirax [®]) and dasabuvir (Exviera [®]) SMC No. 1051/15 Full submission	For use in combination with dasabuvir (Exviera [®]) with or without ribavirin for the treatment of genotype 1 chronic hepatitis C (CHC) in adults and for use in combination with ribavirin for the treatment of genotype 4 CHC in adults.	Hospital Only Hepatitis Team Gastroenterology Specialist List	SMC advice SPC link (Exviera) SPC link (Viekirax)
paclitaxel albumin (Abraxane [®]) SMC No. 1071/15 No submission	In combination with carboplatin for the first-line treatment of non-small cell lung cancer in adult patients who are not candidates for potentially curative surgery and/or radiation therapy.	Not recommended	SMC advice
secukinumab (Cosentyx [®]) SMC No. 1054/15 Full submission	For the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.	Hospital Only Dermatology Clinic Dermatology Specialist List	SMC advice SPC link

* 'pending' means that no local recommendation to support use is in place at the current time.

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 \(including Individual Patient Treatment Requests\)](#).

Updates from previous SMC Advice

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
vedolizumab 300mg powder for concentrate for solution for infusion (Entyvio [®]) SMC No. 1045/15 Full submission	For the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNF α) antagonist.	Hospital Only Gastroenterology Specialist List	SMC advice SPC link <i>For patients who have failed to respond or relapsed with infliximab or golimumab.</i>
golimumab, 50mg and 100mg solution for injection (Simponi [®]) SMC No. 946/13 Full submission	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.	Hospital Only Gastroenterology Specialist List	NICE MTA 329 (February 2015)
infliximab 100mg powder for concentrate solution for infusion (Remicade [®]) SMC No. 374/07 Resubmission	Treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.	Hospital Only Gastroenterology Specialist List	NICE MTA 329 (February 2015)



Tayside Area Formulary (TAF) Updates - June 2015

TAF Section	Drug(s)/Topic	Changes
Specialist Formulary Lists	General Surgery	General Surgery Specialist Formulary List added. Includes medicines approved for prescribing by or on the recommendation of a Consultant Surgeon (for Colorectal, Upper GI or Vascular Surgery). Further details of corresponding formulary changes are listed throughout this table under the relevant formulary section.
	Substance Misuse	Substance Misuse Specialist Formulary List added. Includes medicines approved for prescribing by or on the recommendation of a Consultant from Tayside Substance Misuse Service (TSMS).
01.03.05	Esomeprazole (intravenous)	Administration as intravenous injection added to formulary (previously only intravenous infusion listed) and General Surgery Specialist Formulary List (Hospital Only) as intravenous PPI for patients Nil by Mouth.
01.05.03	Cytokine modulators	Golimumab and infliximab added to formulary and Gastroenterology specialist formulary list (Hospital Only) for moderately to severe active ulcerative colitis in adults in accordance with NICE MTA 329 .
01.05.03	Vedolizumab	Vedolizumab added to formulary and Gastroenterology specialist formulary list (Hospital Only) for adults with moderately to severe active ulcerative colitis who have failed to respond or relapsed with infliximab or golimumab. See SMC advice on page 3.
01.07.04	Management of anal fissures	Glyceryl trinitrate rectal ointment 0.2% (unlicensed), glyceryl trinitrate rectal ointment 0.4%, and diltiazem rectal cream 2% (unlicensed) added to formulary and General Surgery Specialist Formulary List (GPs may prescribe under the direction of a Consultant Surgeon).
02.05.01	Iloprost injection	Iloprost injection for infusion (unlicensed) added to formulary and General Surgery specialist formulary list (Hospital Only).
Chapter 3 - Respiratory system	COPD	Chapter Links: NHS Tayside Respiratory MCN Inhaled Medicine Chart updated.
03.01.01.01	Long-acting beta ₂ agonists - Chronic Obstructive Pulmonary Disease	Salmeterol now non-formulary. Olodaterol (Striverdi® Respimat®) added to formulary. All medicines within this sub-section given equal formulary status (as per updated Respiratory MCN Inhaled Medicine Chart).
03.01.02	Antimuscarinic bronchodilators - Chronic Obstructive Pulmonary Disease	Tiotropium as Spiriva® HandiHaler® now non-formulary. Tiotropium as Spiriva® Respimat® added to formulary. Umeclidinium (Incruse® Ellipta®) added to formulary. All medicines within this sub-section given equal formulary status.
03.01.04	Compound bronchodilator preparations	Umeclidinium and vilanterol (Anoro® Ellipta®) added to formulary. All medicines within this sub-section given equal formulary status.
03.02	Compound preparations - Chronic Obstructive Pulmonary Disease	All medicines within this sub-section given equal formulary status.
04.06	Domperidone and metoclopramide	Postoperative ileus indication added [unlicensed use 'off-label'] (Hospital only) to formulary and General Surgery specialist formulary list.
04.06	Other drugs for Ménière's disease	Higher than licensed dosage for licensed indications (Vertigo, tinnitus and hearing loss associated with Ménière's disease) in patients not responding to standard dose treatment who do not have adverse effects at standard dosage added to formulary and ENT Specialist Formulary List (GPs may prescribe under the direction of an ENT surgeon). Link to local protocol added.

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TAF Updates - June 2015 (continued)

TAF Section	Drug(s)/Topic	Changes
06.01.02.04	Dipeptidylpeptidase-4 inhibitors (DPP-4 inhibitors)	Sitagliptin now first choice DPP-4 inhibitor. Alogliptin and alogliptin with metformin (Vipdomet [®]) added to formulary. Alogliptin now second choice DPP-4 inhibitor. Saxagliptin and saxagliptin with metformin (Komboglyze [®]) now non-formulary.
06.01.02.05	Glucagon-like peptide-1 receptor agonists (GLP1-RA)	Liraglutide now listed as first choice GLP1-RA and lixisenatide listed as second choice GLP1-RA. Exenatide once weekly M/R injection (Bydureon [®]) added to formulary in a new sub-section - Glucagon-like peptide-1 receptor agonists - once weekly .
06.01.02.06	Sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors)	Dapagliflozin now listed as first choice SGLT2 inhibitor and canagliflozin listed as second choice SGLT2 inhibitor. Wording in formulary notes for dapagliflozin and canagliflozin amended to be consistent with manufacturers SPCs.
08.03.04.03	Somatostatin analogues	Management of gastrointestinal secretions [unlicensed use 'off-label'] added to octreotide and lanreotide formulary entries and General Surgery specialist formulary list (Hospital only).
09.01.01.02	Ferric Carboxymaltose (Ferinject [®])	Further indication added to formulary and General Surgery specialist list – to increase haemoglobin reserves prior to surgery in patients at risk of low haemoglobin post-op [unlicensed use 'off-label'].
09.05.05	Selenium	Selenium ACE [®] +D added to formulary (Hospital Only) as Selenium ACE [®] discontinued.
09.05.01.03	Magnesium Glycerophosphate	Formulary choice of magnesium glycerophosphate tablets changed to chewable tablets (MagnaPhate [®]) (4mmol of magnesium per tablet). This product is classed as a food supplement, however is manufactured under GMP conditions. Magnesium glycerophosphate 1mmol/mL oral solution [unlicensed] added to formulary and General Surgery specialist formulary list (GPs may prescribe under specialist direction).
13.5.3	Drugs affecting the immune response	<p>Apremilast (Otezla[®]) added to formulary and Dermatology specialist formulary list (Hospital Only) for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including narrowband ultraviolet B, psoralen and ultraviolet-A (PUVA), acitretin, methotrexate and ciclosporin. See SMC advice on page 2.</p> <p>Secukinumab (Cosentyx[®]) added to formulary and Dermatology specialist formulary list (Hospital Only) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy and who have failed to respond to standard systemic therapies (including ciclosporin, methotrexate, narrowband UVB phototherapy and PUVA), or are intolerant to, or have a contraindication to these treatments. See SMC advice on page 3.</p>
Chapter 17	Non-BNF	Gastrografin [®] gastroenteral solution added to formulary and General Surgery specialist list - Hospital Only (once-only use under the direction of a Consultant Surgeon) [unlicensed use].

SMC Briefing Note:

[Click here](#) for June Briefing Note

[Forthcoming SMC Advice](#)

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