



### Special Points of Interest for Primary Care

#### SMC Advice - May:

- Adalimumab (Humira®)
- Budesonide (Budenofalk®)
- Collagenase clostridium histolyticum (Xiapex®)
- Dexamethasone (Ozurdex®)
- Entacavir (Baraclude®)
- Idelalisib Zydelig®
- Insulin degludec (Tresiba®)
- Linagliptin (Trajenta®)
- Liraglutide (Victoza®)
- Ofatumumab (Arzerra®)
- Vedolizumab (Entyvio®)

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## Drug Safety Updates

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

### Hydroxyzine: Risk of QT Interval Prolongation & Torsade de Pointes

A European wide review has concluded that hydroxyzine is associated with a small risk of QT interval prolongation and Torsade de Pointes.

The maximum daily dose for hydroxyzine is now 100mg. Daily doses of above 100mg were licensed for anxiety but its use in anxiety is not recommended.

Hydroxyzine is listed as a green traffic light in the formulary for pruritis.

Previous advice was caution use in the elderly and patients with susceptibility to QT interval prolongation.

The main changes are:

- contra-indicated in patients with QT interval prolongation or risk factors for QT interval prolongation
- avoid use in the elderly
- maximum daily dose is now
  - ◆ 100mg for adults
  - ◆ 50mg for the elderly ( if use can't be avoided)
  - ◆ 2mg/kg body weight for children up to 40kg in weight
- **prescribe the lowest effective dose for as short a time as possible**

For further information [Click Here](#)

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Adalimumab (Humira®) SMC No. 1050/15  <i>Abbreviated submission</i>	For the treatment of active enthesitis-related arthritis in patients, 6 years or age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.	<b>Hospital Use Only</b> (Paediatric Rheumatology)  (Will not appear in TAF which is an adult formulary)	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Budesonide (Budenofalk®) SMC No. 1043/15  <i>Full submission</i>	For the treatment for the indication autoimmune hepatitis (AIH). The company requests that this submission is assessed as 'selective by population' for those patients who decline or cannot tolerate steroids (first line therapy) and are non-cirrhotic patients with severe (actual or anticipated) steroid-related side effects such as psychosis, poorly controlled diabetes or osteoporosis.	<b>Non Formulary</b> - absence of clinician demand	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Collagenase clostridium histolyticum (Xiapex) SMC No. 1059/15  <i>Non submission</i>	Treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.	<b>Not Recommended</b>	<a href="#">SMC advice</a>
Dexamethasone (Ozurdex®) SMC No. 1046/15  <i>Full submission</i>	For the treatment of adult patients with visual impairment due to diabetic macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.	<b>Non Formulary</b> - lack of clinician support	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Entacavir (Baraclude®) SMC No. 1049/15  <i>Abbreviated submission</i>	For the treatment of chronic HBV infection in nucleoside naive paediatric patients from 2 to 18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of moderate to severe inflammation and/or fibrosis.	<b>Hospital Use Only</b> (Under direction of Liver team at Aberdeen's children's hospital & King's college hospital London)	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Idelalisib (Zydelig®) SMC No. 1039/15  <i>Full submission</i>	For the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment.	<b>Non Formulary</b> - Absence of clinician demand	<a href="#">SMC advice</a> <a href="#">SPC link (100mg)</a> <a href="#">SPC link (150mg)</a>

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

Medicine	Indication	Local Recommendation Category	Comments and Useful Links
Insulin degludec (Tresiba) SMC No. 1060/15  <i>Non submission</i>	Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year.	<b>Not Recommended</b>	<a href="#">SMC advice</a>
Linagliptin (Trajenta®) SMC No. 850/13  <i>Resubmission</i>	For type 2 diabetes mellitus to improve glycaemic control in adults in combination with insulin with or without metformin.	<b>Non Formulary</b> - Lack of clinician support	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Liraglutide (Victoza®) SMC No. 1044/15  <i>Full submission</i>	For the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with: oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.	<b>Formulary</b> - GPs under direction of Diabetes Clinic. (Endocrine Specialist List)	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Ofatumumab (Arzerra®) SMC No. 1037/15  <i>Full submission</i>	For the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy.	<b>Non Formulary</b> - lack of clinician support	<a href="#">SMC advice</a> <a href="#">SPC link</a>
Vedolizumab (Entyvio®) SMC No. 1045/15  <i>Full submission</i>	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 (TNFα) antagonist.  Also indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist.  A submission for this indication is currently undergoing SMC assessment.	<b>Non formulary</b> - absence of clinician demand	<a href="#">SMC advice</a> <a href="#">SPC link</a>

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## Updates from previous SMC Advice

**No updates this month.**

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



# Tayside Area Formulary (TAF) Updates - May 2015

TAF Section	Drug(s)/Topic	Changes
<a href="#">02.08.02</a>	Oral anticoagulants	Prescribing notes added on drug interactions including link to <a href="#">BNF Appendix 1 (Anticoagulants)</a> . Note added on appropriate measure of renal function for adjusting drug dosages as per <a href="#">BNF advice</a> .
<a href="#">03.04.01</a>	Hydroxyzine	Link to <a href="#">MHRA advice: risk of QT interval prolongation and Torsade de Pointes, April 2015</a> added.
<a href="#">04.01.01</a>	Temazepam	Link to <a href="#">Tayside Prescriber No. 135: Temazepam Prescribing Change - 1 June 2015</a> added.
<a href="#">04.10.03</a>	Opioid dependence	Buprenorphine sublingual tablets, buprenorphine and naloxone (Suboxone®) sublingual tablets, lofexidine hydrochloride tablets, and naltrexone hydrochloride tablets added to formulary (Amber traffic light) in line with the <a href="#">NICE pathway, Drug Misuse, April 2014</a> .  Naloxone (Prenoxad®) injection added to formulary (Green traffic light). Link to <a href="#">NHS Tayside PGD for the supply of naloxone 2mg/2ml injection</a> added (intranet (Staffnet) only access).

## SMC Briefing Note:

[Click here](#) for May Briefing Note

## Forthcoming SMC Advice

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

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