TAYSIDE PRESCRIBER

ADTC Supplement No 175 - August 2019

Timolol 0.5% Strength

Timolol 0.25% eye drops (twice daily preparation) and Timoptol® LA 0.25% ophthalmic gel-forming solution (once daily preparation) are similar in efficacy compared to the 0.5% strengths but with reduced risk of adverse effects.

As part of the Ophthalmology formulary review, timolol 0.5% eye drops and Timoptol® LA 0.5% have therefore been removed from the formulary. Stable patients prescribed the timolol 0.5% eye drops or Timoptol® LA 0.5% may be maintained on these, but **all new patients should be commenced on the 0.25% strength**.

Timolol 0.1% eye gel (Tiopex®) can be recommended if a preservative-free option is required.

Ophthalmology Formulary Review

The Ophthalmology section of the formulary (Chapter 11) and Ophthalmology specialist list have been updated. The key changes are:

- **Ofloxacin eye drops** have replaced ciprofloxacin eye drops for corneal ulcers.
- Gentamicin 1.5% eye drops (unlicensed) (Hospital Only - Red traffic light) added for corneal ulcers.
- Aciclovir eye ointment is due to be withdrawn so **ganciclovir eye gel** should be used as an alternative for viral keratitis. Links added for further information.
- Travoprost eye drops added as an alternative to latanoprost for second-line treatment of glaucoma.
- Recommendation to **use 0.25% timolol eye drops in preference to 0.5%.**
- Optive® replaced by **Optive® Fusion** as a second line ocular lubricant. It is a combination product which also contains sodium hyaluronate.
- Sodium chloride 5% eye drops added for corneal oedema.

Direct-acting Oral Anticoagulants (DOACs) and Antiphospholipid Syndrome (APS)

An EU review has concluded that the use of DOACs in patients with APS could be associated with increased rates of recurrent thrombotic events compared with therapy with a vitamin K antagonist. The SPCs for individual DOACs have been updated to advise against use of DOACs in patients with a history of thrombosis and APS. Further information can be found in June's Drug Safety Update.

Locally, DOACs are not recommended as first line treatment for any patient with APS. From the study data to date there is a significant increased risk of recurrent arterial thrombosis in APS patients when treated with DOACs compared to warfarin. If the primary indication for anticoagulation is a history of arterial thrombosis then patients with APS on DOACs should be strongly considered for warfarin as an alternative anticoagulant.

Remember to report all serious suspected adverse drug reactions with DOACs, including any cases of thromboembolic events due to lack of efficacy, on a Yellow Card.

Pancreatin (Creon®) 40,000

Mylan, the marketing authorisation holder for Creon® has discontinued manufacture of Creon® 40,000 capsules from June 2019. Creon® 10,000 and 25,000 capsules will still be available. Creon® capsules are interchangeable and patients taking the 40,000 capsules can achieve the higher dose by switching to a lower strength capsule and taking more of the lower strength capsules (to achieve the same dose or nearest obtainable dose).

Switching patients to Creon® 25,000 capsules would result in a lower pill burden than switching patients to Creon® 10,000 capsules.
For patients with pancreatic exocrine insufficiency the dose typically required is Creon® 25,000 capsules - 4 capsules with meals and 2 capsules with snacks and milky drinks. Doses are adjusted according to individual requirements.

For further information see local guidance on initiating pancreatic enzymes in adults (Staffnet intranet link only).

Respiratory Formulary Review

Chapter 3 (Respiratory system) of the formulary and the Respiratory Specialist list have been reviewed and rationalised to reflect the most up to date evidence and guidance.

The inhaled medicine charts for COPD and Asthma have been reviewed and updated.
A new hospital protocol for intrapleural dornase alfa (rhDNase) and alteplase for empyema or complicated parapneumonic effusion [unlicensed] under the direction of a Consultant Respiratory Physician, has been linked to the dornase alfa and alteplase formulary entries and added to the Respiratory specialist list (this indication has been added as Hospital-Only).

Key Messages COPD

- **Long-acting antimuscarinic bronchodilators (LAMA) are recommended in combination with long-acting beta-2 agonists (LABA) (as a dual acting bronchodilator device (LABA/LAMA)) for management of breathlessness in COPD. All single agent LAMAs for COPD are now non-formulary:** glycopyrronium (Seebri Breezhaler®), tiotropium (Spiriva® Respimat®), umeclidinium (Incruse Ellipta®), and aclidinium (Eklira Genuair®). Please note: Spiriva® Respimat® remains on formulary for use in asthma as per BTS/ SIGN guidance.
- **Patients currently prescribed a single agent LAMA for COPD should continue until their next Respiratory review.**
- **Indacaterol and glycopyrronium (Ultibro® Breezhaler®) is now non-formulary** as other options (tiotropium and olodaterol (Spiolto Respimat®) (aerosol) and umeclidinium and vilanterol (Anoro® Ellipta®) (dry powder) are preferred.
- **Patients currently appropriately prescribed Ultibro® Breezhaler® may remain on this.**
- **Acetylcysteine 600mg effervescent tablets (NACSYS®) should be reviewed 4 weeks after initiation and only continued if symptomatic improvement** (e.g. reduction in frequency of cough and sputum production).
- **Where NACSYS® is continued; consider stopping treatment at regular intervals (e.g. Respiratory annual review) to check continued benefit.**

Key Messages Asthma

- **Kelhale® (beclometasone dipropionate) is now formulary first choice single agent corticosteroid metered-dose inhaler (MDI) option for asthma.** Kelhale® has extra-fine particles, is more potent than traditional beclomethasone dipropionate CFC containing inhalers, and is approximately twice as potent as Clenil Modulite®. Kelhale® is therapeutically equivalent to Qvar®. Kelhale® is not licensed for use in patients under18 years of age.
- Qvar® remains on formulary as second choice single agent corticosteroid MDI option for asthma. Qvar® is not licensed for use in children less than 12 years of age.

For full information on any of the drugs listed below use the link to the Scottish Medicines Consortium (SMC) website below to search by generic, brand or SMC no.
See NHS Tayside 'Local Decisions on SMC Advice' database (link below) for full details on Board decisions - these are currently listed alphabetically by page.

SMC Advice

Published 13 May 2019

Abemaciclib 50mg, 100mg and 150mg tablets (Verzenios®) SMC2135 and SMC2179
Cariprazine 1.5mg, 3mg, 4.5mg and 6mg hard capsules (Reagila®) SMC2137
Latanoprost 50 micrograms/mL plus timolol 5mg/mL preservative free eye drops (Fixapost®) SMC2159
Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC2144

SMC 'Not recommended' medicines - May2019

Chenodeoxycholic acid 250mg hard capsules (Chenodeoxycholic acid Leadiant®) SMC2190
Daratumumab 20 mg/mL concentrate for solution for infusion (Darzalex®) SMC2191
Dasatinib 20mg / 50mg / 80mg / 100mg and 140mg film-coated tablets (Sprycel®) SMC2192
Doxylamine succinate 10mg and pyridoxine hydrochloride 10mg gastro-resistant tablets (Xonvea®) SMC2140
Rituximab 100mg Concentrate for Solution for Infusion (MabThera®) SMC2193

Published 10 June 2019

Benralizumab 30mg solution for injection in pre filled syringe (Fasenra®) SMC2155
Brigatinib 30mg, 90mg and 180mg film-coated tablets (Alunbrig®) SMC2147
Durvalumab 50mg/mL concentrate for solution for infusion (Imfinzi®) SMC2156
Fingolimod 0.25mg, 0.5mg hard capsules (Gilenya®) SMC2154
Fluticasone propionate/formoterol fumarate metered dose inhaler 50 microgram/5 microgram (Flutiform®) SMC2178
Nivolumab 10mg/ml concentrate for solution for dilution (Opdivo®) SMC2153
Patisiran 2mg/mL concentrate for solution for infusion (Onpattro®) SMC2157

SMC 'Not recommended' medicines - June 2019

Alirocumab 75mg / 150mg solution for injection in pre-filled pen (Praluent®) SMC2201
Brentuximab vedotin 50mg powder for concentrate for solution for infusion (Adcetris®) SMC2202
Golimumab 50mg solution for injection in pre-filled pen / 50mg solution for injection in pre-filled syringe (Simponi®) SMC2203

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Area Drug and Therapeutics Committee. Please direct any queries to:

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New & Updated Formulary Links

- Dexamethasone Dosing Information for Hameln brand (May 2019)
- Specials Recommended by the British Association of Dermatologists (BAD) for Skin Disease 2018
- MHRA Drug Safety Update. Valproate medicines and serious harms in pregnancy: new Annual Risk Acknowledgement Form and clinical guidance from professional bodies to support compliance with the Pregnancy prevention Programme, April 2019

Other Formulary Updates

- Nifedipine immediate release capsule formulation removed from formulary entry in calcium channel blockers section as discontinued
- Semaglutide 0.25mg, 0.5mg, 1mg solution for injection in pre-filled pen (Ozempic®▼) added to formulary (Amber traffic light) as 1st choice weekly GLP-1 receptor agonist. Dulaglutide (Trulicity®▼) changed from 1st choice to 2nd choice weekly GLP-1 receptor agonist. Exenatide (Bydureon®) (was 2nd choice) now non-formulary (may be continued in existing patients)
- Non-formulary entry for micronised progesterone 100mg oral capsules (Utrogestan®) updated to include restricted indication (Amber traffic light) – may be prescribed 2nd line under direction of Tayside Menopause clinic as per local protocol
- Benzoyl peroxide 4% and 5% cream and 10% gel for acne now non-formulary as discontinued. Benzoyl peroxide 5% gel remains on formulary
- Anthelios® XL cream SPF 50+ now non-formulary as it has been discontinued and reformulated to Anthelios® Ultra Cream SPF50+ which is not currently available on prescription

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.

Links to Additional Information

Monthly Drug Safety Updates:
www.gov.uk/government/publications/drug-safety-update-monthly-newsletter

For full details of medicines and forthcoming SMC Advice see SMC Website:
www.scottishmedicines.org.uk

For a Summary of a Product's Characteristics (SPCs) see Electronic Medicines Compendium Website:
http://www.medicines.org.uk/emc/

For full details on NHS Board decisions see Tayside Area Formulary - Local Decisions on SMC Advice database:
http://www.nhstaysideadtc.scot.nhs.uk/approved/formular/NewMeds Homepage.htm

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the Policy on Prescribing of Non-Formulary Medicines (including PACS Tier 1 & 2)