Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary – June 2017

Monthly News Update

Welcome to the KINES Monthly News Update for June 2017. **KINES articles are also available online via the KINES Evidence Service website, which healthcare professionals in CCGs that are Optum ScriptSwitch™ users can register to access here.** Other recent 'KINES Updates' have discussed:

- The NOR-SWITCH study – a Norwegian government-funded study which has provided evidence to support the switching of patients who are stable on originator infliximab treatment to biosimilar infliximab (*Link to KINES article – login required*)
- An analysis reporting that use, including short-term use, of any NSAID was associated with an increased risk of acute myocardial infarction, reinforcing the need for particular caution in prescribing NSAIDs to any person with relatively high risks of cardiovascular disease. (*Link to KINES*)
- A Cochrane review comparing LABA/LAMA and LABA/ICS therapy, the findings of which support the evolving place of dual LABA/LAMA bronchodilators in the management of COPD. (*Link to KINES*)

Update from NICE:

- NICE is currently consulting the next update to its medicines optimisation Key Therapeutic Topics (KTTs). It is proposed that the KTT on 'lipid modifying drugs' is retired and the 'standardisation of chemotherapy doses and products' is added. Feedback can be submitted until 14th July 2017.
- An evidence summary has been published for liraglutide (Saxenda) for use in weight management. The manufacturer (NovoNordisk) has reported that they will only promote the use of this treatment on private prescription, so they anticipate that use on the NHS will be limited. An evidence summary has been published for bezlotoxumab (Zinplava), a new monoclonal antibody treatment for preventing the recurrence of *Clostridium difficile* infection.

Regulatory agency safety update:

- The MHRA has advised that patients prescribed the rosacea treatment brimonidine gel (Mirvaso) should be warned not to apply the product to irritated or damaged skin, including after laser therapy. Cases of systemic cardiovascular effects, including bradycardia, hypotension and dizziness, some requiring hospitalisation, have been reported after application of bromonidine, which is an α-2 adrenergic agonist. Some cases followed laser procedures, which possibly caused increased absorption of brimonidine.
- The MHRA has recommended that osteonecrosis of the external auditory canal should be considered as a possibility in patients receiving denosumab (Prolia; Xgeva) presenting with ear symptoms. Possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma. Patients should be advised to report any ear pain, discharge or infection during treatment. There have been a rare number of reports (5 worldwide) of osteonecrosis of the external auditory canal and the product information for denosumab is being updated with this warning.
- Healthcare professionals and the public are being encouraged to use the Yellow Card website to report any suspected side effects or safety concerns with e-cigarettes and e-liquids for vaping, including harms to children and non-users, and device defects. The MHRA is responsible for the notification scheme for these products, which must now comply with the standards in the Tobacco Products Directive that was introduced last month.
- The European Medicines Agency has started a review of the multiple sclerosis treatment Zinbryta (daclizumab), focusing on liver damage – a known adverse effect for which several measures are already in place to minimise risk. While the review is ongoing, healthcare professionals are advised to closely monitor their patients and discuss with them the risk of liver damage and possible symptoms.

NHS England/Department of Health/Public Health England:

- As circulating flu has returned to baseline levels, the Department of Health has announced that primary care should no longer prescribe, and community pharmacists should no longer supply, flu antivirals on FP10s.
- Public Health England (PHE) has issued guidance for primary care on the diagnosis and laboratory investigation of fungal skin and nail infections. A Word version is available for local adaptation and a quick reference table has also been provided. PHE has also published guidance on the range of child and maternal health data and intelligence resources available to help commissioners and healthcare professionals plan local services health for children,

young people and pregnant women. Finally, tobacco profiles have been refreshed for England; local data can be benchmarked via an interactive tool.

- New PHE resources include patient leaflets on measles, mumps and rubella vaccine, promoting immunisation of new mothers, and 'Flu vaccination: who should have it this winter and why'. A summary chart indicating which flu vaccine children should have has also been published.

Other news:

- Care homes may be interested in the Dementia Assessment Referral to GP (DeAR-GP) tool. The resource helps care workers in identifying people who are showing signs of dementia or confusion through use of a brief cognitive test and acts as a communication aide with the patient's GP or healthcare professional for referral for a review.

Other news:

Launched

- Eluxadoline tablets(Truberzi) have been launched for the treatment of irritable bowel syndrome with diarrhoea in adults. In draft guidance published in February, NICE did not recommended eluxadoline. Final NICE guidance is expected to be published on the 30 August 2017.
- The obesity treatment Mysimba (naltrexone/bupropion 8 mg/90 mg sustained-release tablets) has also been launched. It is licensed as an adjunct to diet and exercise for weight management in adults with a BMI of: ≥30kg/m^2 (obese); or ≥27kg/m^2 to <30kg/m^2 (overweight) with at least one weight-related comorbidity. 28 days' treatment at the maintenance dose of 2 tablets morning and evening costs £73.00 (MIMS, June-17). Treatment should be discontinued if there is <5% weight loss after 16 weeks. In draft guidance published last month, NICE did not recommend Mysimba, citing concerns about the validity of the economic analysis. Final NICE guidance is expected to be published on 23rd August 2017.
- A further salmeterol/fluticasone inhaler has been launched for use in asthma - an aerosol (pMDI) formulation of AirFluSal Forspiro. Two strengths are available:
  -AirFluSal 25 µg salmeterol/125 µg fluticasone propionate
  -AirFluSal 25 µg salmeterol/250 µg fluticasone propionate
  AirFluSal MDIs are not licensed for use in under 18 year olds. The devices may be used with either Volumatic or AeroChamber Plus spacers. The inhalers have been priced the same as the Sereflo salmeterol/fluticasone MDIs launched last month. Brand name prescribing is recommended to ensure patients are supplied with the correct device.

Current options for salmeterol/fluticasone pMDIs:	*Cost/inhaler (120 puffs). MIMS June-17*
Lower ICS (25 µg salmeterol/50 µg fluticasone propionate)	
Seretide Evohaler 50	£18.00
Mid ICS (25 µg salmeterol/125 µg fluticasone propionate)	
AirFluSal MDI 25/125	£23.50
Sereflo 25/125	£23.50
Sirdupla 25/125	£26.25
Seretide Evohaler 125	£35.00
Higher ICS (25 µg salmeterol/250 µg fluticasone propionate)	
AirFluSal MDI 25/250	£39.95
Sereflo 25/250	£39.95
Sirdupla 25/250	£44.60
Seretide Evohaler 250	£59.48

Other drug updates:

- The patent covering the use of **Lyrica (pregabalin)** in neuropathic pain will expire next month on the **17th of July 2017**. ***Keele's comment:*** We are aware that recommendations on pregabalin prescribing differ between CCGs, and prescribers should consult their local medicines optimisation teams for guidance. For example, some CCGs may prefer that prescribers continue to prescribe lower cost branded generics to seek maximum savings whilst awaiting the category M price of pregabalin to fall (*we are unable to anticipate how quickly this will happen or by how much this will be*). Branded generics include **Axalid** (*this is currently the lowest priced pregabalin product [£19.95 for 56 capsules, all dose strengths]*), Alzain (£24.95 for 56 capsules, all dose strengths) and Rewisca (£45.40, 56 capsules all dose strengths). Other CCGs may prefer that prescriptions for pregabalin are all written generically. NHS England has also now issued updated guidance on pregabalin.
- Protelos (strontium ranelate 2g granules for oral suspension) is to be discontinued in August. The Specialist Pharmacy Service (SPS) has issued a memo which discusses alternatives.
- New risk management materials have been made available for Valdoxan (agomelatine). The materials focus on liver function monitoring (a pathway has been produced) and drug interactions (concomitant use of potent CYP1A2 inhibitors [e.g. fluvoxamine, ciprofloxacin] is contraindicated).

SMC Update *(Please see links for full SMC advice.)*:

- The Scottish Medicines Consortium (SMC) has published the following advice this month:
  - **Accepted for use in NHS Scotland:** adalimumab (Humira; *acne inversa in adolescents*); aprepitant (Emend; *nausea/vomiting in chemotherapy in children*); budesonide-formoterol (Symbicort SMART; *asthma, extension to children 12 to <18 years*); cabozantinib (Cabometyx; *renal cell carcinoma*); nivolumab (Opdivo; *renal cell carcinoma*); obeticholic acid (Ocaliva; *primary biliary cholangitis*)
  - **Accepted for restricted use:** buprenorphine oral lyophilisate (Espranor; *opioid drug dependence*); deferasirox (Exjade; *iron overload*)
  - **Not recommended:** ibrutinib (Imbruvica; *chronic lymphocytic leukaemia*); pertuzumab (Perjeta; *breast cancer*); safinamide (Xadago; *Parkinson's Disease*).