Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary March 2017

Monthly News Update

Welcome to the KINES Monthly News Update for March 2017. Other recent 'KINES Updates' have covered:

- An intervention by a CCG to reduce unnecessary liver function testing for statins, which resulted in considerable cost-savings.
- An analysis of patient safety incidents involving children in primary care in England and Wales, which has flagged the provision of medications as an area for improvement.
- The recent systematic review and meta-analysis on vitamin D for the prevention of acute respiratory infections.

Update from NICE:

- NICE has updated the familial breast cancer guideline (CG164). The main change is that anastrazole is now also included amongst recommended preventative treatments. (*Within primary care, GPs may be asked to prescribe chemoprevention following an assessment of breast cancer risk in secondary care or by genetics clinics.*) For women at **high** risk of breast cancer, the key recommendations regarding chemoprevention are:
  - Offer tamoxifen for 5 years to **premenopausal** women unless they have a past history or may be at increased risk of thromboembolic disease or endometrial cancer.
  - Offer anastrozole for 5 years to **postmenopausal** women unless they have severe osteoporosis.
  - For postmenopausal women who have severe osteoporosis or do not wish to take anastrozole: offer tamoxifen for 5 years if they have no history or increased risk of thromboembolic disease or endometrial cancer, or consider raloxifene for 5 years for women with a uterus if they have no history or increased risk of thromboembolic disease and do not wish to take tamoxifen.

  For women at **moderate** risk of breast cancer, the recommendations are similar, except the advice is to 'consider' their use, rather than 'offer'. See the guideline for all updates.
  The use of chemoprevention is a preference-sensitive decision, and to help women make an informed choice, NICE has published a set of new decision aids, and an accompanying user guide, based on this latest update to the guideline. These are available on the resources page for the guideline.
- NICE has published new guidance on spondyloarthritis (NG65). The guideline covers recognition and referral in non-specialist settings, including criteria for when to refer a patient for spondyloarthritis assessment.
- NICE evidence summaries have been published on the off-label use of rituximab in the treatment of systemic sclerosis/localised scleroderma, and oxybutynin in hyperhidrosis. Summaries have also been published on the new medicines opicapone, which is licensed for use in patients with Parkinson's disease with end-of-dose motor fluctuations, and pitolisant for the treatment of narcolepsy.

Regulatory agency safety update:

- The European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has started a new review of valproate use in pregnancy and women of childbearing age. Measures to strengthen the warnings and restrictions on valproate were introduced in 2014. However, concerns have been raised about their effectiveness, and this new review will consider whether further action should be recommended.
- In line with the EMA's conclusions, the MHRA has now issued national advice on the risk of lower-limb amputation with the type 2 diabetes treatment canagliflozin. Whilst the evidence does not show an increased risk for dapagliflozin and empagliflozin, this may be a class effect of sodium-glucose co-transporter 2 (SGLT2) inhibitors. Preventative foot care guidance should be followed, and patients receiving canagliflozin, who have risk factors for amputation, should be carefully monitored. Consider stopping canagliflozin if a patient develops foot complications, such as infections, skin ulcers, osteomyelitis or gangrene.

NHS England/Department of Health/Public Health England:

- Among the measures included the 2017-19 Quality Premium scheme for CCGs is the reduction of Gram-negative bloodstream infections (BSIs) and inappropriate antibiotic prescribing in at risk groups. Performance will be assessed in three parts: a) CCG-level reports of *E. coli* BSIs; b) reductions in the prescribing of trimethoprim for urinary tract infections (UTIs) (*the metrics for which are reductions in the trimethoprim:nitrofurantoin prescribing ratio and trimethoprim items prescribed to patients age 70 or over*); and c) sustained reductions in inappropriate antibiotic prescribing (*measured as a CCG's prescribing rate to be equal or below 2013/14 levels for England*). Further information on these metrics, including baseline and target values for CCGs, is available in two new Excel

files: Part a) reducing Gram-negative BSIs across the whole health economy and Part b) reduction of inappropriate antibiotic prescribing for UTIs in primary care.

- Due to a worldwide shortage, unlicensed BCG vaccine is currently being imported for use in the UK. Public Health England guidance on use of this product has recently been updated, including advice on vaccine administration.
- A consultation is currently open on proposals to allow schools to hold spare adrenaline auto-injectors. Feedback can be submitted until 5th May.
- Details of the national flu immunisation programme plan for 2017/18 for England have been published. Changes include the roll-out of the programme to children in school year 4. Vaccination of the morbidly obese (BMI of 40 and above) will attract a payment under the directed enhanced services in 2017/18.
- Prescription prices in England will change from April 2017, increasing by 20p from £8.40 to £8.60. Cost of prepayment certificates remain the same.

Other news:

- The Centre for Postgraduate Pharmacy Education has published a new guide aimed at pharmacist prescribers on Prescribing: maintaining competence and confidence.
- UKMi has published an in-use safety assessment for Ultibro Breezhaler (indacaterol/glycopyrronium inhalation powder, which is licensed for use in COPD). The report suggests that patients should be informed of the 30-day expiry date that applies to the Breezhaler delivery device (which is different to the expiry date for the active capsules), to minimise the risk of using the device beyond this period.
- The Faculty for Sexual and Reproductive Healthcare has updated their clinical guideline on emergency contraception.

Drug Update:

Launched

- Fiasp, a faster acting formulation of insulin aspart, has been launched in the UK by NovoNordisk. Fiasp is a mealtime insulin, which can be administered up to 2 minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal. Due to its earlier onset of action, hypoglycaemia may occur with Fiasp earlier after an injection/infusion when compared with other mealtime insulins (Fiasp SPC). It has been priced equivalent to NovoNordisk's NovoRapid insulin aspart.
- Aerivio Spiromax (50 microgram salmeterol/500 microgram fluticasone propionate) dry powder inhaler has been launched by Teva. It is the second bioequivalent alternative to Seretide 500 Accuhaler to become available, the first being AirFluSal Forspiro. Costs are shown below – Aerivio is the lowest priced. Brand name prescribing is recommended to avoid confusion between these inhalers.

Product	Licensed Indications	Use in children	30 day cost (1 inhalation, twice daily) (MIMS [3/17])
Seretide 500 Accuhaler	Regular treatment of asthma where long acting β_2-agonist and inhaled corticosteroid is appropriate. Symptomatic treatment of COPD in patients with a pre-bronchodilator FEV_1 <60% predicted and a history of exacerbations and with significant symptoms despite regular bronchodilator therapy.	For asthma, can be used in adolescents 12 years and older.	£40.92
AirFluSal Forspiro	As per Seretide 500 Accuhaler	Safety & efficacy in children and adolescents < 18 years not established.	£32.74
Aerivio Spiromax	As per Seretide 500 Accuhaler	Safety & efficacy in children and adolescents <18 years not established.	£29.97

SPC changes / license extensions

- The SPC for Jentadueto (linagliptin/metformin) has been updated to include information on use of linagliptin as an add-on to a combination of metformin and empagliflozin. *(We note the current NICE treatment algorithm for type 2 diabetes [from NICE guideline 28] does not include the triple therapy combination of metformin, a gliptin and an SGLT2 inhibitor. The next update to NG28 will be undertaken by a new standing committee for the guideline and will consider the effectiveness of SGLT2 inhibitors and GLP1 mimetics on cardiovascular outcomes. The update is due to be published in December 2017.)*

AWMSG/SMC Update *(Please see below verdicts for full advice)*:

- The Scottish Medicines Consortium (SMC) has published the following advice this month:
  - Accepted for use in NHS Scotland: obinutuzumab (Gazyvaro; follicular lymphoma)
  - Not recommended: abatacept (Orencia; rheumatoid arthritis not previously treated with methotrexate); lacosamide (Vimpat; monotherapy indication in epilepsy); liposomal irinotecan (Onivyde; pancreatic cancer).
- The All Wales Medicines Strategy Group Consortium (AWMSG) has published the following advice this month:
  - Recommended as an option: aflibercept (Eylea; myopic choroidal neovascularisation); triptorelin (Decapeptyl SR; adjuvant/neoadjuvant in prostate cancer); migalastat (Galafold; Fabry disease; AWMSG agreed to adopt NICE's recommendations).