Important New Evidence Service

In Partnership with The Centre for Medicines Optimisation at Keele University

ScriptSwitch Monthly Summary February 2018

Monthly News Update

Welcome to the KINES Monthly News Update for February 2018.

Other recent KINES Updates have discussed (*ScriptSwitch Users, login or register to access*):

- A cohort study that found a lower risk of dementia in people with atrial fibrillation (AF) who took oral anticoagulants. Although further research is needed to confirm the findings of this observational study, this may provide another reason for a person with AF to choose to take an oral anticoagulant.
- A UK study that found many people taking an aldosterone antagonist were not monitored in line with guideline recommendations.
- A study investigating the incidence of fatalities due to adverse drug reactions. Within the hospital that was the setting for this study, 1 in 15 of all inpatient deaths were considered to be associated with medicines.

Update from NICE:

- In final guidance, NICE has **not** recommended lesinurad (Zurampic) for the treatment of hyperuricaemia (*N.B. this product has been licensed but not launched in the UK [ref: SPS website*]). NICE's review committee noted that the clinical evidence did not show that lesinurad plus allopurinol improved clinically important outcomes (such as number of flares and tophi healing) compared with allopurinol alone.
- NICE has published dose tables for inhaled corticosteroids (ICS) to support the recent NICE asthma guideline. These indicate the 'low', 'moderate' and 'high' doses of different ICS for adults and children. It is perhaps worth noting that whilst the *guideline* gives recommendations on treatment of children and young people aged 5 to 16 years of age, the *tables* give dosages for children aged 5 to 11 years. This reflects the age categories used in most of the UK marketing authorisations for ICS inhalers. It is expected that in clinical practice a prescriber will choose dosages for young people aged between 12 to 16 years taking into account factors, such as the severity of their condition and their size compared with the average for their age group.

Regulatory agency safety update:

- The following safety measures are temporarily in place for Esmya (ulipristal acetate) 5 mg tablets (used in the treatment of uterine fibroids), whilst the European Medicines Agency (EMA) carries out a safety review following several reports of serious liver injury.
    - **Do not initiate new treatment courses of Esmya**, including for women who have previously completed treatment courses,
    - **Perform liver function tests (LFTs) at least once a month in all women currently taking Esmya.** Stop treatment if transaminase levels > 2 times the upper limit of normal (ULN), closely monitor and refer for specialist hepatology evaluation as clinically indicated. LFTs should be repeated 2 to 4 weeks after stopping treatment.
    - Check transaminase levels immediately in current or recent users who present with signs/symptoms suggestive of liver injury (nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice). If transaminase levels >2 ULN, stop treatment, closely monitor and refer for specialist hepatology evaluation as clinically indicated.
    - Advise women using Esmya on the signs and symptoms of liver injury.

  This advice applies to Esmya only. The MHRA states there have been no cases of serious liver injury reported for the emergency contraceptive ellaOne (single-dose, 30 mg ulipristal acetate). Whilst this review is ongoing, NICE has issued an update to the guideline on heavy menstrual bleeding to remind prescribers to read the guidance in conjunction with the temporary safety measures. The Summary of Product Characteristics for Esmya has also now been updated to warn that hepatic impairment is likely to increase drug exposure and to include recommendations on LFTs.

- It is likely that additional measures to support the avoidance of valproate in pregnancy will soon be introduced. This is in light of recent recommendations from the EMA's pharmacovigilance risk assessment committee (PRAC), which included new restrictions on use, a pregnancy prevention program and changes to product packing. Further advice is anticipated from the MHRA in the coming weeks.

NHS England/Department of Health and Social Care/Public Health England:

- Following conclusion of a public consultation on gluten-free (GF) prescribing, the Department for Health and Social Care (DHSC) has decided that patients who are allergic to gluten will now only be able to be prescribed GF bread and flour mixes. This means that GF foods from the following categories will no longer be available for prescribing: biscuits, cereals, cooking aids, grains/flours and pasta. Work will begin on amending regulations and then removing these products from the Drug Tariff.
  Keele's comment: Some CCGs may have developed local GF prescribing policies, which may, in some cases, recommend limiting prescribing beyond that announced by the DHSC. Feedback from NHS Clinical Commissioners comments that the DHSC decision does not affect the statutory authority that a CCG has to determine the availability of GF foods in their local area.
- NHS prescription charges will rise from the 1st April 2018 from £8.60 to £8.80. The costs of the 3- and 12-month prescription prepayment certificates remain unchanged at £29.10 and £104, respectively.
- Public Health England recently published a report on a new Return on Investment (ROI) Tool for Falls Prevention Programmes for Older People in the Community. This report is potentially of interest to CCGs and local authorities considering investing in such programmes. All four programmes included in the report were found to produce a positive societal ROI, with one programme (*home assessment and modification*) also found to have a positive financial ROI (i.e. cost savings outweighing implementation cost).
- NHS England has recently corresponded with GP practices and community pharmacists about the ordering of influenza vaccines for the next flu season. For the 2018/19 winter season, the recommended vaccines will be:
  - adjuvanted trivalent vaccine for all 65s and over
  - quadrivalent vaccine for 18 to under 65s at risk (*it is also used for the childhood programme*)
- Practices are being asked to review all orders (both provisional and firm) for the next season, to ensure they are in line with these new recommendations.

Other news:

- SPS has published an 'In use product safety assessment report' for Onexila XL (oxycodone once daily prolonged release tablets). The report notes the potential for confusion between this once daily preparation and other modified release preparations of oxycodone, all of which have twice daily dosing regimens. Brand name prescribing, and a review of local prescribing and dispensing systems (*for example to highlight products' dosing regimens*) are among the suggested actions to help reduce risk of confusion.

Medicines update:

Launched

- The first generic version of glatiramer acetate has been launched for the treatment of multiple sclerosis, which is marketed under the brand name Brabio by Mylan.

  Keele comment: We note that NICE are currently reviewing glatiramer acetate (and beta interferons); final guidance is expected in May 2018.