NHS Hampshire, Southampton and Isle of Wight Clinical Commissioning Group
NHS Portsmouth Clinical Commissioning Group

Prescribing and Medicines Optimisation Guidance

Issue: 72 **Date: 29th June 2022**

1. DOAC patent challenge – key message Edoxaban remains routine preferred DOAC for stroke prevention in AF

You may be aware that two generic suppliers have challenged the UK patents currently in place for the direct oral anticoagulant (DOAC), apixaban. These court proceedings resulted in the patent held by Bristol Myers Squibb (BMS), being declared invalid. BMS has filed its application to seek permission to appeal to the Court of Appeal. There are no set timelines for the Court of Appeal to issue a decision and currently an appeal hearing has not been set. Therefore, this remains an ongoing process and there is significant uncertainty about the timescales and outcome of the appeals process.

You may also be aware that a generic version of apixaban has been made available to wholesalers from the end of May. However, it is important to understand:

- the generic version of apixaban has been made available at a small discount against the originator list price (i.e. nowhere near a typical generic discount of 80+%).
- there is limited supply.

Edoxaban remains the best value DOAC by a considerable margin.

Neither the price at which the generic version of apixaban has been made available nor its limited supply justifies the NHS to change the existing commissioning recommendations that were issued in January 2022.

Edoxaban remains the first choice for stroke prevention atrial fibrillation for new patients, where clinically appropriate.

2. Intravaginal Progesterone for HRT

Intravaginal progesterone is prescribed as part of HRT treatment to prevent endometrial hyperplasia and cancer. Although the British Menopause Society suggests intravaginal progesterone may be an option to consider in HRT regimens, other menopause guidelines, including NICE and European, international and

American guidelines do not make any specific recommendations for PV administration of progesterone.

The Medicines Evaluation Committee (MEC) reviewed the evidence available. Most of the studies are in assisted reproduction indications and evidence is much more limited for HRT indications, resulting in uncertainty as to whether the desired outcome of prevention of endometrial hyperplasia (and cancer) will be achieved. We must remember why we are prescribing this, and that is to stop iatrogenic endometrial cancer. While there are numerous studies looking at the blood levels of intravaginal progesterone's, these are in the area of assisted reproduction. The mucosa and hence absorption cannot be extrapolated from a hormone-rich patient undergoing reproductive treatment to a potentially atrophic situation. Indeed, the very few studies that have been done in this 'menopausal group' show mixed results in terms of levels, from acceptable, to variable consistency, to inadequate. The suggestion that uterine progesterone levels are elevated by intravaginal administration is unproven particularly in the post and peri-menopausal group.

The MEC concluded that there is no evidence that this route of administration offers proven protection. A 'suggestion' of effect is not enough when considering NOT giving patients endometrial cancer. Until there is data proving safety, the MEC advise against this usage, for the safety of our patients. Based on these recommendations the **District Prescribing Committee (DPC) do not support the use of intravaginal progesterone for HRT as they do not feel there is sufficient evidence for this.**

3. Management of iron deficiency anaemia

Please note guidelines by the British Society of Gastroenterology guidelines for the management of iron deficiency anaemia in adults.

British Society of Gastroenterology guidelines for the management of iron deficiency anaemia in adults | Gut (bmj.com)

The guidelines recommend the use of oral iron ONCE DAILY to treat iron deficiency anaemia. Some secondary care providers have updated their management to using once daily iron preparations and so this may also be seen in patients transferred to primary care.

4. SPS update: Using proton pump inhibitors (PPIs) alongside warfarin – clinical considerations (Link)

This resource considers the management and clinical impact on anticoagulation when prescribing PPIs with warfarin. It outlines the evidence and mechanism for the interaction, choosing a suitable PPI, monitoring when initiating and stopping a PPI, and counselling points.

5. NEWT guidelines

The NEWT Guidelines Website offers advice for administration of medication to patients with enteral feeding tubes or swallowing difficulties. The subscription for NEWT has now been renewed to include Portsmouth clinicians. Please speak to your Medicines Optimisation teams for access details.

To log in to the site, go to www.newtguidelines.com and click on the “Registered users” button.

Prepared by Anita Bhardwaj, Sue Wakelin and Dr Emma Harris
On behalf of the Hampshire, Southampton and IoW CCG Medicines Optimisation Team

Previous bulletins can be found at: https://gp-portal.westhampshireccg.nhs.uk/medicines/covid-19-medicines-information/covid-19-medicines-optimisation-bulletins/