South East London Area Prescribing Committee

Temporary withdrawal of formulary recommendation number 056 (Originally issued January 2018, re-issued November 2019): Ulipristal acetate 5mg tablets (Esmya®) for the intermittent treatment of moderate to severe uterine fibroids in women of reproductive age

This formulary recommendation has been **temporarily withdrawn** in view of the ongoing safety concerns with ulipristal acetate 5mg tablets (Esmya™) and a new safety review being undertaken by the European Medicines Agency (EMA). **The licence for ulipristal 5mg tablets has been temporarily suspended throughout the EU during the review.**

The EMA has started its review at the request of the European Commission following a recent case of liver injury, which led to liver transplantation in a patient taking the medicine. A 2018 EMA review concluded that there is a risk of rare but serious liver injury with ulipristal 5mg for the treatment of uterine fibroids, and measures were implemented to minimise the risk.

However, as the new case of serious liver injury occurred in spite of adherence to these measures, the EMA has started a new review.

To protect patients while a safety review is conducted, the EMA's safety committee, the Pharmacovigilance Risk Assessment Committee, (PRAC) has recommended that **women stop taking 5mg ulipristal tablets for uterine fibroids**.

Additionally, **no new treatment courses of ulipristal 5mg tablets should be started.**

The MHRA has issued a **patient level recall** outlining the specific actions to be undertaken by healthcare professionals and patients.

The decision to temporarily withdraw this formulary recommendation will be reviewed once the EMA review has concluded.

Please refer to the EMA website and MHRA CAS alert for further information and detail.

Note 1: Esmya is licensed for the pre-operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.
Note 2: This advice does not affect the 30mg single dose ulipristal acetate emergency contraceptive products.

19th March 2020