Rationale for Initiation, Continuation and Discontinuation (RICaD)

Progesterone (micronised) - Utrogestan®

Adjunctive use with oestrogen in post-menopausal women with an intact uterus. (HRT)

This document supports the use and transfer of an agent which is classified as **AMBER**.
It is intended for completion by specialists in order to give Primary Care prescribers a clear indication of the reason for recommending an **AMBER** medication together with suggested criteria for its subsequent continuation or discontinuation. This RICaD should be provided as a supplement to the specialist's clinical letter.

Patient details		**GP details**		**Specialist details**	
Name		**GP Name**	**Dr**	**Specialist Name**	
NHS Number		**GP address**		**I confirm that this patient is eligible to receive Utrogestan® under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Relevant Diagnosis:	Menopausal symptoms
Agreed Indication(s) for inclusion in the BSSE APC Formulary:	Hormone replacement therapy in patients intolerant of other progestogens. **This patient fits all the following criteria detailed below: Please check boxes to confirm** • Patient is at increased risk of breast cancer or VTE. ☐ **AND** • Patient is intolerant of medroxyprogesterone. ☐ **AND** • Patient has declined Mirena®coil. ☐ (Please refer to algorithm in Appendix A for more detailed information).
Reason why Utrogestan® has been chosen in preference to drugs without Formulary restrictions:	Allows for titration of progestogen independent of oestrogen management. Also in patients with a BRCA 1 or BRCA 2 mutations and other recognised risk factors for breast cancer this agent carries a lower risk. NICE guidance on HRT recommends transdermal oestrogen and combination products only include norethisterone or levonorgestrel. Where these are not tolerated or patient requirements sit outside of available combination products Utrogestan® offers the most cost effective, flexible and least complicated alternative progesterone management.
Pre-treatment test results	Not Applicable

Guidance on initiation

Initiation dose:	• 100mg daily at bedtime from day 1 to day 25 for continuous combined regimes **OR** • 200mg daily at bedtime, for twelve days in the last half of each therapeutic cycle (beginning on day 15 of the cycle and ending on day 26) • Utrogestan® capsules should not be taken with food and should be taken at bedtime. Concomitant food ingestion increases the bioavailability of Utrogestan® capsules.

Monitoring:	Unscheduled bleeding should be investigated after 3 months of treatment. Ophthalmic examinations and migraine during therapy. Fluid retention. Breast examination/screening.

Suggested Criteria for Continuation or Discontinuation

Assessment of Efficacy	
Frequency	6 monthly
Location	Outpatients clinic/GP practice
Method (what tests are required)	Clinical assessment and patient reports of symptom control. No biochemical monitoring required
Continuation Criteria	Symptom control with treatment
Discontinuation Criteria	Reported loss of efficacy Ophthalmic concerns (see cautions section) Increase fluid retention (see cautions section)
Follow up action	Refer to BWH Menopause clinic
Shared Care Read Code	In the patients notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing
SystmOne	XaB58	Shared care

Please note the information included in this document is correct at the time of writing. The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.

Appendix A

UTROGESTAN ® IN MENOPAUSE MANAGEMENT

Patients presenting to Menopausal Clinic will routinely be offered Elleste Duet® or Elleste Conti® a combined oestradiol and norethisterone preparation unless one or more of the following considerations applies (cohort 2000 pts per annum)

Patients at increased risk of breast cancer[1] or VTE[2] first line recommendation 10%

Patients requiring > 2mg of oestrogen per day will require separate progestogen. Medroxyprogesterone will be offered initially. Norethisterone is only available at too high a dose for this indication

Patients demonstrating intolerance to Medroxyprogesterone, will be offered Mirena Coil

Patient Declines Mirena® Coil

10%

Patients qualifying for Utrogestan ® First line plus those who decline Mirena ® coil and are intolerant to Medroxyprogesterone
Total 20%

Patients meeting the criteria for commencing Utrogestan® would be prescribed Utrogestan® in primary care on the recommendation of the specialist as an **amber** category drug.

Annual Cost of 28 days of medroxyprogesterone acetate for 400 patients is £16,560
Cost of 28 days of Utrogestan® for 400 patients is £19,680
Additional annual treatment cost is £3,120 for identified cohort of patients referred to specialist clinic

1. Fournier A et al, Int J Cancer 2005; 114: 448–454
2. Canonico M et al, Circulation 2007;115:840-845

Based on HeFT RICaD template
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Appendix B: Important Information from the Summary of Product Characteristics

Special precautions	**Contraindication:** • Known allergy or hypersensitivity to progesterone or to any of the excipients. • Severe hepatic dysfunction. • Undiagnosed vaginal bleeding. • Mammary or genital tract carcinoma. • Thrombophlebitis. • Thromboembolic disorders. • Cerebral haemorrhage. • Porphyria. **Cautions:** Utrogestan® should be used cautiously in patients with conditions that might be aggravated by fluid retention (e.g. hypertension, cardiac disease, renal disease, epilepsy, migraine, asthma); in patients with a history of depression, diabetes, mild to moderate hepatic dysfunction, migraine or photosensitivity and in breast- feeding mothers. • Utrogestan® capsules are not suitable for use as a contraceptive. • If unexplained, sudden or gradual, partial or complete loss of vision, proptosis or diplopia, papilloedema, retinal vascular lesions or migraine occurs during therapy, the drug should be discontinued and appropriate diagnostic and therapeutic measures instituted. • Utrogestan® capsules are intended to be co-prescribed with an oestrogen product as HRT. Epidemiological evidence suggests that the use of HRT is associated with an increased risk of developing deep vein thrombosis (DVT) or pulmonary embolism. The prescribing information for the co-prescribed oestrogen product should be referred to for information about the risks of venous thromboembolism. • There is suggestive evidence of a small increased risk of breast cancer with oestrogen replacement therapy. It is not known whether concurrent progesterone influences the risk of cancer in post-menopausal women taking hormone replacement therapy. The prescribing information for the co-prescribed oestrogen product should be referred to for information about the risks of breast cancer.
References:	Utrogestan® SPC http://www.medicines.org.uk/emc/medicine/19895 (accessed March 2016)