BRIEFING SHEET FOR PRIMARY CARE

RELUGOLIX 40MG, ESTRADIOL HEMIHYDRATE 1MG AND NORETHISTERONE ACETATE 0.5 MILLIGRAMS (RYEQO®)

INTRODUCTION

The NICE technology appraisal (NICE TA832) recommends relugolix–estradiol–norethisterone acetate (RYEQO®), within its marketing authorisation, as an option for:

- treating moderate to severe symptoms of uterine fibroids in adults of reproductive age.
- symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis

As per local formulary agreement, Ryeqo® initiation should be via a uterine fibroid or endometriosis specialist.

TRAFFIC LIGHT CLASSIFICATION

Ryeqo® is classified as GREEN for these indications.

SPECIALIST TEAM INITIATION

As per local agreement the specialist team will:

- Initiate and supply two months' supply of Ryeqo®. Inform the GP at the point of initiation that Ryeqo® has been prescribed (as per NICE TA832)
- Complete a pregnancy test before initiation of treatment
- Provide the patient with initial information/counselling regarding the treatment and possible adverse effects:
    - This includes the risk of arterial or venous thromboembolism (and to report any signs or symptoms to a healthcare professional).
- Stop any hormonal contraception prior to starting Ryeqo® and inform the patient around appropriate non hormonal contraceptive use in the first month and for a week after two missed doses.
- Advise patients to contact their doctor if they experience mood changes and depressive symptoms during treatment. In women with a history of depression carefully monitor for recurrent depression.
- In exceptionally high risk patients, a baseline DEXA will be carried out prior to initiation, this will be reviewed by the specialist and actioned if necessary.

There is a requirement for a DXA scan to be completed after 12 months of treatment. This will be ordered by the specialist and the decision to stop or continue treatment should be clearly communicated to the patient's GP. If there is no unwanted degree of bone mineral density loss, the patient can be safely discharged to the their GP (whilst remaining available for any future queries).

DOSE

One tablet of Ryeqo must be taken once daily, at about the same time with or without food.

DURATION OF TREATMENT

Ryeqo can continue indefinitely as long as the drug is effective or until instructed to stop via the specialist. If treatment is discontinued, please contact the gynaecology team and inform the patient that childbearing potential will return rapidly. Discontinuation should be considered when the patient enters menopause.

MONITORING

There is no specific drug monitoring required for Ryeqo®. Primary care clinicians should review their patients as per normal practice and be aware of any adverse effects which the patient may report to them (see adverse effects table above).

Ryeqo® is contraindicated in pregnancy and should be stopped if a patient becomes pregnant.
Breastfeeding is contraindicated during the use of Ryeqo® and for 2 weeks following discontinuation

Written and approved by East Suffolk and North Essex NHS Foundation Trust (ESNEFT), West Suffolk Foundation Trust (WSFT)
SNEE Integrated Care Board
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SIDE EFFECTS

Refer to the SPC and the BNF for full list of side effects.

Adverse Effect	Frequency	Suggested Management by GP
Irritability	Common	Monitor and if patient cannot tolerate, consider stopping treatment and refer back to the gynaecology team. Inform patient they will need to use non-hormonal contraception methods if Ryeqo® is stopped.
Hot flush	Common	
Dyspepsia	Common	
Alopecia	Common	
Hyperhidrosis	Common	
Night sweats	Common	
Uterine bleeding including menorrhagia and metrorrhagia	Common	
Decreased libido	Common	
Breast cyst	Common	Stop and refer for a breast scan or to breast team for review. Inform the initiating team and inform patient they will need to use non-hormonal contraception methods if Ryeqo® is stopped.
Uterine myoma expulsion	Uncommon	Stop treatment and refer back to hospital team. inform patient they will need to use non-hormonal contraception methods if Ryeqo® is stopped.
Hypertension	Rare	Although small increases in blood pressure have been reported in women taking Ryeqo, clinically relevant increases are rare. If sustained clinically significant hypertension develops during treatment, hypertension should be treated and the benefit of continued therapy should be assessed by the specialist. If treatment is discontinued, use may be resumed if normotensive values can be chieved with antihypertensive treatment

References
1. Ryeqo 40mg/1mg/0.5mg film-coated tablets Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/12934
2. BNF. Available at: https://bnf.nice.org.uk/drugs/relugolix-with-estradiol-and-norethisterone-acetate/