HERTFORDSHIRE AND WEST ESSEX AREA PRESCRIBING COMMITTEE (HWE APC)

RELUGOLIX-ESTRADIOL-NORETHISTERONE ACETATE FOR TREATING MODERATE TO SEVERE SYMPTOMS OF UTERINE FIBROIDS

(NICE TA 832)

**AMBER INITIATION - RECOMMENDED FOR RESTRICTED USE.
INITIATION AND STABILISATION BY SPECIALISTS.
CONTINUATION IN PRIMARY CARE FOLLOWING STABILISATION OF THERAPY, AND AFTER AN ASSESSMENT OF TOLERABILITY AND EFFICACY HAS BEEN MADE BY THE SPECIALIST.**

Name: generic (trade)	What it is	Indication	Date decision last revised	Decision status	NICE / SMC Guidance
Relugolix-estradiol-norethisterone **(Ryeqo®)**	*Relugolix*: a non-peptide GnRH receptor antagonist *Estradiol*: an exogenous estradiol and agonist of the nuclear estrogen receptor *Norethisterone*: a synthetic progestogen	Licensed for treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age	December 2022	Final	NICE TA 832 - recommended

HWE APC recommendation:

Relugolix–estradiol–norethisterone acetate is recommended, within its marketing authorisation, as an option for treating moderate to severe symptoms of uterine fibroids in adults of reproductive age, in line with the recommendations in TA832.

Relugolix–estradiol–norethisterone acetate can be considered when standard non-hormonal (for example tranexamic acid, NSAIDs) and hormonal pharmacologic options (for example levonorgestrel-releasing intrauterine system, combined hormonal contraception, cyclical oral progestogens) as detailed in NICE guidance 88 'Heavy menstrual bleeding: assessment and management' are unsuitable /ineffective AND the next treatment options would be injectable gonadotrophin-releasing hormone (GnRH) agonists, uterine artery embolization/surgical interventions.

AMBER INITIATION:
RECOMMENDED FOR RESTRICTED USE. INITIATION AND STABILISATION BY SPECIALISTS.
Specialists must also counsel the patient at initiation on all aspects related to the safe and effective use of this medication. This includes information to the patient on ongoing recommended monitoring such as but not limited to, the recommendation for a DXA scan after 1year of treatment.
CONTINUATION IN PRIMARY CARE FOLLOWING STABILISATION OF THERAPY, AND AFTER AN ASSESSMENT OF TOLERABILITY AND EFFICACY HAS BEEN MADE BY THE SPECIALIST.

NICE TA 832 recommendations:
Relugolix–estradiol–norethisterone acetate is recommended, within its marketing authorisation, as an option for treating moderate to severe symptoms of uterine fibroids in adults of reproductive age.

Further information: (for latest updates and more detailed information please refer to summary of product characteristics SPC)
The SPC includes some contra-indications and cautions for use and indicates that at **initiation**, in patients with risk factors for osteoporosis or bone loss, a DXA scan is recommended prior to starting treatment, a complete medical history (including family history) must be taken, blood pressure must be measured and a

physical examination must be performed guided by the contraindications and warnings for use. Advice on contraception must be provided (provides adequate contraception after at least one month of treatment; any hormonal contraception needs to be stopped prior to initiation of treatment, as concomitant use of hormonal contraceptives is contraindicated. Non-hormonal methods of contraception must be used for at least 1 month after initiation of treatment.) Pregnancy must be ruled out.

During treatment, periodic check-ups must be carried out according to standard clinical practice.
A DXA scan is recommended after 1 year of treatment to verify that the patient does not have an unwanted degree of bone mineral density loss, that exceeds the benefit of treatment with relugolix-estradiol-norethisterone.

At **discontinuation,** alternative contraception needs to be started immediately. (Women of childbearing potential must be advised that ovulation will return rapidly after discontinuing treatment). Discontinuation should be considered when the patient enters menopause

Current treatment as per NICE guidance 88 Heavy menstrual bleeding, note non-hormonal and hormonal pharmacological options (e.g. tranexamic acid or NSAIDS, levonorgestrel-releasing intrauterine system, combined hormonal contraception, cyclical oral progesterone), GnRH agonists or surgical options.