Surrey Heartlands Integrated Care System Area Prescribing Committee (APC)

INFORMATION SHEET – Blue Traffic Light Classification	
Name of medicine	Dienogest
Indication (including whether for adults and/or children)	**Management of endometriosis and associated pain symptoms**

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The information sheet is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface for medicines classified by Area Prescribing Committee (APC) as **BLUE**

BLUE drugs are considered suitable for prescribing in primary care, following initiation and stabilisation by a specialist as ongoing monitoring can be undertaken in primary care without specialist support and WITHOUT the need for a formal shared care guideline.
For each drug classified as **BLUE**, the Area Prescribing Committee will recommend the minimum supply and whether an information sheet is required or not. A minimum of one month supply of medication will be provided by the initiating consultant.
This information sheet sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications. A GP or Primary Care Prescriber must ensure they are familiar with the prescribing responsibilities. This information sheet is available on the internet **http://pad.res360.net/** forming part of the Prescribing Advisory Database (PAD) giving GPs appropriate advice / guidance and is not required to be sent to the GP with the clinic letter.

RESPONSIBILITIES and ROLES

Consultant / Specialist responsibilities	
1.	To assess the suitability of patient for treatment
2.	To discuss the aims, benefits, and side effects of treatment with the patient and/or carer as well as their role
3.	Explain to the patient and/or carer the treatment plan including the dosing schedule and request for transfer of care to GP
4.	Assessment of risk of osteoporosis
4.	Specialist to prescribe dienogest for at least 6 months before requesting transfer of prescribing of dienogest to the primary care prescriber
5.	Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan
6.	Supply GP with summary of patient review (including anticipated length of treatment) and a copy of any information sheet available
7.	Advise GP if treatment is to discontinue at any point
8.	Specialist to advise primary care prescriber on vitamin D & calcium supplements to prescribe to reduce negative effects on BMD
9.	Inform GP if patient does not attend planned follow-up
10.	Define any characteristics of clinical response that can be reviewed by GP to assess response to drug
11.	Consider a DEXA scan for patients continuing long term therapy

General Practitioner (GP) or Primary Care Prescriber responsibilities	
1.	Subsequent prescribing of dienogest in primary care
2.	Primary care to prescribe vitamin D & calcium supplements (as advised) to reduce negative effects on BMD
3.	Stop all hormonal contraceptives – Discuss alternative options for contraception with the patient.
4.	Respond to advice based on DEXA scan results, in line with PAD guidance

Patient / Carer role	
1.	Informing the specialist team, primary care prescriber or other healthcare professional if he or she has further questions or

	wants more information about the treatment
2.	Tell the consultant / specialist or GP or Primary Care Prescriber of any other medication being taken, including over-the-counter products.
3.	Sharing any concerns about their treatment and problems they are having taking their medicines with the specialist team, primary care prescriber or other healthcare professional involved in their care
4.	Discuss alternative contraceptive options with their GP or primary care prescriber as appropriate
5.	Supported to know how to report any adverse effects to the specialist team, primary care prescriber or other healthcare professional involved in their care, and how adverse effects can be managed
6.	To be available for monitoring as required
7.	Attend follow-up appointments with the consultant / specialist / GP. **Non-attendance of appointments may result in treatment being stopped**

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available here https://mhraproductsprod.blob.core.windows.net/docs-20200128/0b4820e1847c23be8f8bd1c16501b1e6301b1467 for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication (www.nhs.uk)

Endometriosis is a condition where tissue, similar to the lining of the womb, starts to grow in other places, such as the ovaries and fallopian tubes.
Endometriosis can affect women of any age.

It is a long-term condition that can have a significant impact on your life, but there are treatments that can help.

Dienogest acts on endometriosis by reducing the endogenous production of oestradiol and thereby suppresses the trophic effects of estradiol on both the eutopic and ectopic endometrium. When given continuously, dienogest leads to a hypoestrogenic, hypergestagenic endocrine environment causing initial decidualization of endometrial tissue followed by atrophy of endometriotic lesions (information from evidence review discussed at APC in November 2021)

Indication
Management of endometriosis and associated pain symptoms

Dosage and Administration
Refer to current Summary of Product Characteristics (SPC) available here: https://mhraproductsprod.blob.core.windows.net/docs-20200128/0b4820e1847c23be8f8bd1c16501b1e6301b1467

Expected outcome
Reduction in pain associated with endometriosis

Monitoring

Test	Frequency	Abnormal Result	Action if Abnormal Result
XXXXX	XXXXX	XXXXX	XXXXX

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC): Link to SPC as above

Adverse effects - Refer to current Summary of Product Characteristics (SPC): Link to SPC as above

Drug interactions - Refer to current Summary of Product Characteristics (SPC): Link to SPC as above

Medical therapy for women with confirmed or suspected Endometriosis

This document does not replace or supersede existing national guidance and recommendations for the investigation and treatment with Endometriosis and Endometriosis associated pain.
It is intended as a pathway for the appropriate prescribing and supervision of medical therapies for endometriosis associated pain

All women to be advised on appropriate use of simple analgesics and anti-inflammatories

All women to be advised that hormonal therapy can be effective at reducing endometriosis associated pain but to take into consideration individual patient factors such as fertility wishes, personal preferences and other medical contraindications or risks
*Surgical treatment for endometriosis should be considered for all women who have confirmed or suspected endometriosis following appropriate counselling of risks and benefits.

There is limited evidence to routinely recommend the use of one hormonal treatment over another but 1st line treatments to be considered/recommended include:
Combined hormonal contraceptive e.g. COCP, contraceptive patch, vaginal ring
Progestogen only e.g. mini-pill, norethisterone, levonorgestrel IUS, etonorgestrel implant

All patients commenced on medical therapy should have either a scheduled review of treatment efficacy or open access (up to 6 months) to a specialist clinic.

Second line therapies to be considered under specialist supervision should include GnRH agonists e.g.Zoladex® OR dienogest OR neuromodulators

Dienogest

Initiation of therapy will be from Secondary care specialist clinics. Therapy should initially be recommended for 3-6 months before considering whether or not to continue as long-term therapy. Other hormonal contraceptives should be discontinued.
A decision to continue on long term treatment can be made either in primary or secondary care and based upon the patient's symptom response.
There is little available evidence for long term therapy (>15 months) and therefore a review in the specialist clinic at 12 monthly intervals is recommended.
Decisions on continuing treatment will be based upon symptoms response, side effect profile, desire for conception/contraception and objective assessment of endometriosis such as size of endometrioma on imaging.
All patients seen in the Endometriosis clinic have 6-month open access to the Consultant clinic after last review.

Supervision of therapy

Long-term therapy (>15 months) may be associated with reduced bone mineral density with particular risk associated with adolescent populations due to effect on peak bone mass.
Individuals at increased risk of osteoporosis (i.e. adolescents, low BMI, smokers, long term steroid therapy) should have a risk assessment performed at initiation of therapy with specialists to consider monitoring at yearly intervals in secondary care with baseline BMD scans with repeat scans considered at 2-3 yearly intervals.
Primary care to support treatments to reduce negative effects on BMD such as Vit D and Calcium supplements https://www.bda.uk.com/resource/calcium.html

Prevention of recurrence of Endometriosis and Endometriosis associated pain

Evidence suggests that both adjunctive (<6months) and long-term hormonal medical therapy (>6months) are effective at reducing the risk of either endometriosis recurrence or the risk of recurrence of endometriosis associated pain following surgical treatment.
There is limited evidence to routinely recommend the selection of one form of hormonal therapy above another, and consideration should be given to fertility desires, woman's preference and other medical comorbidities. However, hormonal options to consider and which are appropriate include: Combined hormonal contraceptives, Progestogen only therapy, including dienogest & GnRH agonists

Surrey Integrated Care System Area Prescribing Committee (in collaboration with partnership organisations)
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