NHS BSW Prescribing guidance for Dienogest (Amber TLS – 1 month)

Bath and North East Somerset, Swindon and Wiltshire Together

Background

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 significantly impacts patients' quality of life.
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.
Expected outcome – Reduction in pain associated with endometriosis.

Dienogest

Initiation will be from Secondary care specialist clinics where 90 days supply will be issued. 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 will be made in secondary care and based upon the patient's symptom response.
A useful literature review which includes evidence regarding long-term use can be found here.
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.
Effects on Bone Mineral Density (advice from local rheumatology specialists):
Some studies show a modest reduction of bone mineral density in patients taking dienogest. The clinical relevance of this in terms of future fracture risk is not established.
If the patient has significant other risk factors for impaired bone health (for example, current use of oral or systemic glucocorticoids, or previous fragility fracture), please consider liaison with your local bone health team to review whether further investigation in the form of a DXA scan may be indicated.
Dienogest 2mg £20.50 for 28 tabs (costs as per Drug Tariff October 2025)

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. Hormonal contraceptives should be stopped – Discuss alternative options for contraception with the patient.
5. Assessment of risk of osteoporosis
6. Specialist to prescribe dienogest for at least 3 months before requesting transfer of prescribing of dienogest to the primary care prescriber
7. Monitor and evaluate response to treatment, including adverse drug reactions, with the patient and to continue / discontinue treatment in line with agreed treatment plan
8. Supply GP with summary of patient review (including anticipated length of treatment) and a copy of any information sheet available
9. Advise GP if treatment is to discontinue at any point
10. Specialist to advise primary care prescriber on vitamin D & calcium supplements to prescribe to reduce negative effects on BMD
11. Inform GP if patient does not attend planned follow-up
12. Define any characteristics of clinical response that can be reviewed by GP to assess response to drug

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/change contraception as per advice from the specialist.

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

Medical Treatment for Endometriosis in Women

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, etonogestrel (Nexplanon®) 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.

Adverse effects:

Undesirable effects are more common during the first months after the start of treatment and subside with continued treatment. There may be changes in bleeding pattern, such as spotting, irregular bleeding or amenorrhea. The most frequently reported undesirable effects are headache, breast discomfort, depressed mood and acne.
For a full list of adverse effect see the SPC here.

Specialist contact information:

Contact via **Cynapsis**