Guideline for Hormone Implant Replacement Therapy

Document Type:	Clinical Guidelines
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Approved By:	**Health Board**
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Version:	1.1

Target Audience:

People who need to know about this document in detail	All health care professionals working in the menopause team / Gynaecology
People who need to have a broad understanding of this document	Womens health directorate team. Board Members, Management Board. Senior Leaders. Board Committees.)
People who need to know that this document exists	All staff involved in the development of Health Board Policies.

Integrated Impact Assessment:

Equality Impact Assessment Date & Outcome	**Date:**
	Outcome:
Welsh Language Standard	Choose an item.
Date of approval by Equality Team:	(00/00/0000)
Aligns to the following Wellbeing of Future Generation Act Objective	Choose an item.

Disclaimer:

If the review date of this document has passed please ensure that the version you are using is the most up to date version either by contacting the author or CTM_Corporate_Governance@wales.nhs.uk

COMPONENTS:

A policy must contain the following components and must also be written to include the values and behaviours of the organisation wherever relevant:

It is accepted that for Clinical Policies and or other Written Control Documents (Procedures, Guidance etc.) the policy components below may not all be relevant.

For guidance on Clinical Policy Development please contact:

CTM_ClinicalPolicies@wales.nhs.uk

For guidance on Non Clinical Policy Development please contact:

CTM_Corporate_Governance@wales.nhs.uk

Or visit the Policy Author Page on SharePoint:

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BACKGROUND

Guideline Definition

Clinical guidelines are systemically developed statements that assist clinicians and patients in making decisions about appropriate treatments for specific conditions.

They allow deviation from a prescribed pathway according to the individual circumstances and where reasons can be clearly demonstrated and documented.

This guideline addresses the use of hormone replacement therapy (HRT) implants, specifically estradiol and testosterone implants, in the management of menopausal and postmenopausal symptoms.

Purpose

To provide a standardised approach:

- ***New patients offered implants
- Patients already receiving implants
- The method for the insertion of hormone implants under local anaesthesia, ensuring patient safety and comfort. The guideline aims to minimise this by standardising the information, advice and treatment that we provide to our patients

Scope

For all staff, medical and nursing, to provide uniformity in the care and treatment of women being administered with hormonal implants.

Roles and Responsibilities

In seeking further advice on any uncertainties contained in this document, or if you feel that there is new or more updated advice it is your responsibility to contact the guideline author or Approval Group manager so that any amendments can be made.

The guideline Approval Group is responsible for disseminating this guideline to all appropriate staff.

The guideline author or a named alternative is responsible for updating the guideline with any amendments that they become aware of or are highlighted to them.

All health professionals are responsible to ensure that the guideline is utilised effectively, and to ensure that they are competent and compassionate in the implementation of it.

Training Requirements

There is no mandatory training associated with this guideline.

Monitoring of Compliance

- By audit and review of complaints relating to HRT Implant management.
- The Governance Department will collate any complaints and distribute to the relevant individuals for comments, and share any learning points.
- The Service Lead will oversee any governance issues, make relevant recommendations to the directorate, and advise the Clinical Director or the directorate of any matters that require implementation.
- The Health Board reserves the right, without notice, to amend any monitoring requirements in order to meet any statutory obligations or the needs of the organisation

Complaints

All complaints should try to be resolved with the patient during any contact to avoid escalation. There concerns should be listened to and documented. If it is not possible to address any concerns at the time, or if the complaint is of a serious nature, the patient's complaint should be discussed with the consultant in charge for the day, or the patient should be given details of how to raise a formal complaint via the local governance department.

Equality Impact Assessment Statement

This policy has been screened for relevance to Equality. No potential negative impact has been identified.

Introduction

Menopause is a natural biological process characterised by the cessation of menstruation and a decline in ovarian hormone production. Symptoms can include hot flushes, night sweats, mood changes, and decreased libido. HRT is commonly used to alleviate these symptoms. However, in cases where other HRT options are ineffective, hormone implants may be considered by specialist menopause services.

Primary candidates

Severe vasomotor/psychological symptoms persisting despite oral/transdermal HRT.

Surgical menopause (especially younger women requiring higher estradiol levels for bone protection)

Contraindications to oral HRT (e.g., BMI >30, history of venous thromboembolism [VTE]).

Testosterone deficiency with hypoactive sexual desire disorder (post conventional HRT trial).

Contraindications

Absolute

- Current/past breast cancer.
- Undiagnosed vaginal bleeding
- Active liver disease
- Hypersensitivity to implant components.
- Avoid in women with uncontrolled thrombosis risk factors
- Avoid in women undergoing cancer investigations

Relative

- History of VTE, cardiovascular disease, or migraines with aura.
- Enzyme-inducing medications (e.g., anticonvulsants, St John's Wort).

Objectives

- To provide evidence-based recommendations for the use of estradiol and testosterone implants in HRT.
- To ensure safe and effective management of menopausal symptoms.
- To support clinicians in making informed treatment decisions.

Evidence Summary

Specialist-led care

- Implants must be managed by menopause specialists due to unlicensed status and complex dosing.
- Insertion intervals: Estradiol 25–50 mg (every 4–6 months); Testosterone 100 mg (every 3–6 months).

Shared decision-making

- Use https://www.nice.org.uk/guidance/ng197 to discuss risks (e.g., local bruising, acne), benefits, and alternatives.
- Document patient preferences using decision aids (e.g., BMS patient leaflets).

Estradiol Implants

- Provide steady hormone levels over 6–8 months.
- Unlicensed in the UK but used under specialist supervision.
- Associated with a small risk of thromboembolic events and stroke, similar to other forms of transdermal HRT.
- Potential for tachyphylaxis (rapid tolerance), with symptoms returning before the next scheduled implant in approximately 3% of cases.

Testosterone Implants

- Indicated for women with Hypoactive Sexual Desire Disorder unresponsive to conventional HRT.
- Unlicensed in the UK; used off-label under specialist supervision.
- Low risk of side effects; most common is reversible facial or body hair growth.
- No licensed testosterone products for women in the UK; use of male formulations is common practice.

Recommendation	Strength	Evidence Level
Testosterone for sexual dysfunction	Conditional	BMS consensus (2022) [3]
Estradiol implants for refractory symptoms	Strong	Historical cohort studies (1984–2021) [1][2]
Avoid oral androgens	Strong	BMS (2022) [3]

Recommendations

Implant Insertion

- Inserted under the skin, typically in the abdomen or buttock.
- Requires local anaesthesia and a small incision.
- Wound closed with steri-strips or dissolvable sutures; sterile dressing applied for 48 hours.
- Refer to CTMUHB Hormone Implant SOP

Monitoring

- Blood tests every 4-6 months to monitor hormone levels.
- Adjust dose or defer implantation if estradiol levels are supraphysiological (>800pmol/L)
- Adjust or defer implantation of testosterone, with a free Androgen index over 5% (calculated from the testosterone and SHBG levels)

Endometrial Protection

- If the patient has a uterus, a progestogen is mandatory to prevent endometrial hyperplasia in patients having Estradiol Implants. This does not apply to patients having Testosterone Implants. In the event that a patient stops using the Estradiol implant, progestogens need to be continued, to ensure endometrial protection, up to two years post insertion of the last Estradiol implant.
- The Mirena® levonorgestrel intrauterine system (IUS) is the gold standard for protection. We recognise that some patients may not wish to have a Mirena IUS and therefore these patients need to be aware that there is no safety data on the use of oral or topical progestogens with Estradiol implants. Prior to using alternative progesterones, the Specialist menopause team will need to advise on regime to ensure adequate dose is prescribed and that the patient is fully informed regarding compliance.
- Regarding oral progestogens, the published data is where synthetic progestogens such as Medroxy Progesterone Acetate (Provera) have been used with implants. There is no published data that we could find on the use of micronized progesterone such as Utrogestan and implants.

Discontinuation

- Implants are non-reversible; removal is not possible once inserted.
- Estradiol implants provide therapeutic effects for 6–8 months; residual implant may continue to release small amounts of estradiol for up to 18–24 months.

Application and Implementation

Clinical Settings

Primary Care

- Initial assessment and referral to specialists.

Specialist Services

- Individual patient assessment and consideration for implant therapy
- Pre-treatment assessment using NICE-approved VTE risk tools [4][5]
- All new patients to be discussed at the Complex Menopause MDT
- Implant insertion and management.
- Comprehensive monitoring and adjustment of therapy

Feasibility and Acceptability

- Consider patient preferences, including comfort with implant procedures and monitoring requirements.
- Discuss potential side effects and the irreversible nature of implants.

Barriers and Strategies

- Limited availability of licensed testosterone products for women Use of male formulations off-label under specialist supervision, in line with GMC and MHRA guidance
- Subcutaneous implants (Estra 25/50mg, Testo-100) remain unlicensed in the UK, with supply restricted pending MHRA review
- Update upon BMS guidance (most recent April 2025) and MHRA guidance
- Shortage in supply of implants: Interim alternatives, Consider transdermal preparations [

Patient-Centered Care

Informed Consent

- Provide clear information about the benefits, risks, and irreversible nature of hormone implants.
- Discuss alternative treatment options, including transdermal and oral HRT.
- Provide information regarding Implants being unlicensed products and its associated risks, providing the following patient information leaflet. https://awttc.nhs.wales/medicines-optimisation-and-safety/medicines-optimisation-guidance-resources-and-data/patient-information-leaflets/understanding-unlicensed-medicines/
- Ensure the appropriate consent form is completed by the patient and clinican and filed in patient notes
- Ensure all discussions are documented in the patient notes.

Shared Decision-Making

All patients have the right to be involved in decisions about their treatment and to make informed decisions if they can. For menopausal women, this means the information healthcare professionals give about HRT should be based on the best available evidence when discussing the risks and benefits of HRT. This should include information about the various ways to take HRT, and an explanation about how any risks are particularly relevant.

Doctors and nurses have a duty to give patients clear, accurate and up-to-date information, based on the best available evidence. Healthcare professionals should utilise the General Medical Council guideline11 and NICE Shared Decision Making guidelines12 to engage patients in discussions about their treatment preferences and values, considering individual risk factors, such as age, medical history, and lifestyle.

Quality of Life Considerations

- Assess the impact of symptoms on daily functioning and well-being.
- Tailor treatment plans to enhance patient quality of life.

References

British Menopause Society (2025) Subcutaneous Hormone Implant Therapy available at: https://thebms.org.uk/2025/02/subcutaneous-hormone-implant-therapy-2/

British Menopause Society (2023) BMS & WHC's 2020 recommendations on hormone replacement therapy in menopausal women, https://thebms.org.uk/wp-content/uploads/2023/10/02-BMS-ConsensusStatement-BMS-WHC-2020-Recommendations-on-HRT-in-menopausal-women-SEPT2023-A.pdf

British Menopause Society (2025) Testosterone replacement in menopause, available at: https://thebms.org.uk/wp-content/uploads/2022/12/08-BMS-TfC-Testosterone-replacement-in-menopause-DEC2022-A.pdf

GMC (2020), Guidance on professional standards and ethics for doctors: Decision making and consent, https://www.gmc-uk.org/-/media/documents/updated-decision-making-and-consent-guidance_pdf-84160128.pdf

Newson Health Menopause Society (2022), Shared decision making as a healthcare professional, https://www.nhmenopausesociety.org/resources/my-doctor-wont-budge-shared-decision-making-with-your-healthcare-professional/

NICE (2024), Menopause: identification and management https://www.nice.org.uk/guidance/ng23/evidence/h-all-cause-mortality-pdf-487915383061

Product Characteristics (SmPC) for Mirena® (2024), https://www.medicines.org.uk/emc/medicine/1829/SPC/Mirena

Stacey, D (2023), All About the Mirena IUD Birth control device that contains the hormone levonorgestrel, https://www.verywellhealth.com/mirena-intrauterine-device-906760#:~:text=Mirena%20is%20a%20hormonal%20intrauterine%20device%20%28IUD%29%20that,eight%20years%20as%20a%20way%20to%20prevent%20pregnancy.

Subcutaneous hormone implants - Jennifer Tamblyn, Lynne Robinson, Eimear Maguire, Alice Hodge, Paula Briggs, 2023

Appendicies

Estradiol Implant Consent Form

ESTRADIOL%20IMPL
ANT%20CONSENT%2

Testosterone Implant Consent Form

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Implant Passport

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Complex Menopause MDT Proforma

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