HERTFORDSHIRE AND WEST ESSEX AREA PRESCRIBING COMMITTEE

(HWE APC)

Medroxyprogesterone acetate (Sayana Press®)

GREEN
Recommended for use in primary and secondary care

NAME: GENERIC (TRADE)	WHAT IT IS	LICENSED INDICATION	DATE DECISION LAST REVISED	DECISION STATUS	NICE GUIDANCE
Medroxyprogesterone Acetate (Sayana® Press)	Long acting reversible progestogen-only injectable	Long term contraceptive purposes in females *(to be administered subcutaneously only)*	HMMC June 2017 WEMOPB January 2018	Final	NICE – no guidance

HMMC and WEMOPB recommendation following consultation with local specialists:
Sayana® Press is recommended as a treatment option when initiating a long-acting reversible progestogen-only injectable for contraceptive purposes in females (use in adolescent females subject to clinical discretion). The first dose is required to be administered by a healthcare professional and if deemed clinically appropriate, following doses can be self-injected by the patient.

Version	1.1 Harmonisation of Hertfordshire Medicines Management Committee (HMMC) guidance and West Essex Medicines Optimisation Programme Board (WEMOPB) guidance updates include: • Rebadging with HWE ICB and removal of WECCG header • Review date removed and replaced with standard statement.
Developed by	HVCCG & ENHCCG & WECCG PMOT
Approved by	HMMC & WEMOPB
Date approved/updated	HMMC June 2017 WEMOPB January 2018
Review date:	The recommendation is based upon the evidence available at the time of publication. This recommendation will be reviewed upon request in the light of new evidence becoming available.
Superseded version	1.0

Sayana® Press

Recommendation

Sayana® Press is recommended as a treatment option when prescribing a long acting reversible progestogen-only injectable for contraceptive purposes in females.This applies to use in primary and secondary care.

Prescribing Rationale

- Sayana® Press is the only parenteral progestogen-only contraception currently available on the UK market which is licensed to be administrated subcutaneously (SC) and can be self-injected by the patient.
- With the exception of the initial dose, which must be administered by a healthcare professional, there is an opportunity for GPs / nurses to counsel suitable patients on how to self-inject on-going doses of Sayana® Press for use outside of a clinical environment. This reduces the need for a healthcare professional to be involved in the drug administration process.
- According to NICE, all currently available long acting reversible contraceptive (LARC) methods (intrauterine devices, the intrauterine system, injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at one year of use. Therefore the former plays a significant role in the helping reduce unintended pregnancies.

Background Information

Sayana® Press:

- Is supplied in a single-dose container which contains 104mg medroxyprogesterone acetate (MPA) in 0.65ml of suspension and is in the form of a Uniject device (a pre-filled injector device).
- Is delivered via SC injection into the anterior thigh or abdomen every 13 weeks (± 7 days) in females (the only parenteral progestogen-only preparation in the UK market licensed to be used via this route).
- Is a white to off-white homogenous suspension.
- Is licensed for long term contraceptive use like Depo-Provera®, an alternative LARC injectable containing 150mg MPA/ml which is injected intramuscularly (IM) once every 12 weeks (± 5 days). Another LARC injection preparation is Noristerat®, which contains 200mg/ml of norethisterone acetate and is injected IM into the gluteal muscle once every eight weeks; however its use in practice is restricted to short term use in selected patient groups.
- Can be recommended in all suitable females, however use in adolescents (12-18 years) should only be considered when other forms of contraceptives have failed or are deemed unsuitable. This is due to unknown long-term effects of bone loss elicited by Sayana® Press and the impact of this on bone growth. The use of Depo-Provera® in this patient group should be also limited to cases were other forms of contraception have been reviewed and deemed unsuitable. For full list of adverse effects refer to SPC
- Has a shelf life of three years if unopened and should be stored at room temperature. Once opened, use immediately and discard any unused portion.

Whilst the initial dose of Sayana® Press should be administered under the supervision of a healthcare professional, future doses can be self-injected by the patient at the discretion of the clinician responsible for care. If the latter is agreed, on-going monitoring is still essential. All patients initiated on Sayana® Press should be carefully counselled on this medication and must be provided with a patient information leaflet. Sayana® Press SPC recommends re-assessment of use in females who wish to continue use for more than two years.

Evidence of Clinical Effectiveness

- The MHRA Public Assessment Report, which confirms the granting of a marketing authorisation for Sayana® Press, states that there is no clinical difference in the pharmacokinetic profile when 104mg/0.65ml MPA-SC is used as a Uniject device or a pre-filled syringe (Sayana® Press was previously formulated as a pre-filled syringe). Therefore studies carried out using the pre-filled syringe version can still be utilised for comparison purposes. On the basis of this, the following statements are made in relation to Sayana® Press: :
  - The product can be regarded as being an effective form of contraception.
  - The side-effect profile was similar to that of alternative contraceptive products on the market
  - Benefit to risk profile has been studied and considered acceptable
- Based on studies using Sayana® Press as a pre-filled syringe, the overall safety profile when using MPA-SC is consistent to that of Depo-Provera®. Furthermore the development of the original pre-filled version of Sayana® Press was based on studies which indicated that 104mg of MPA/0.65ml of suspension injected at three-monthly intervals would reliably suppress ovulation over this time frame.
- In addition to this, no further studies were requested by MHRA to confirm clinical efficacy or clinical safety when Sayana® Press was originally reviewed since it had already gained approval for use as a different formulation. . This endorses the view of Sayana® Press being a suitable treatment option alongside Depo-Provera®.
- Despite Sayana® Press containing less MPA than Depo-Provera®, studies have demonstrated that the former is as effective as Depo-Provera® at preventing unwanted pregnancies.

Cost Effectiveness

- The annual cost of Sayana® Press is marginally more expensive than Depo-Provera® however the former should still be considered as an option in patients who wish to be treated with a parenteral progestogen-only preparation. This is largely due to the degree of flexibility in its dose administration, which is not only more convenient for patients, it can also aid in improving adherence. Additionally, for those patients where self-administration is suitable, this reduces GP / nurse appointment use.

The needs of the population

- All females requiring contraception should be routinely provided information on the different formulations available and are expected to have an input when deciding on preferred method of use.
- The needs of the population can be considered to be low due to the range of other contraceptive preparations available (tablets / implants).
- Since Sayana® Press is administered SC, it can be regarded as being more clinically appropriate for use in the following patient groups:
  - Those at risk of haematoma due to bleeding disorders/anticoagulants.
  - Very obese females in whom there is a concern about IM-MPA reaching the muscle.
- Like all other long-acting reversible contraceptive (LARC) methods, Sayana® Press does not rely on daily concordance, which is beneficial in reducing the number of unintended pregnancies.
- The prescribing of Sayana® Press would permit patients to self-inject at their convenience in accordance to the dosage regimen should their doctor/nurse deem them being competent as doing so.

The needs of the community

There is a small cost implication associated with prescribing Sayana® Press over Depo-Provera® however by utilising the self-administration option of the former, it could potentially reduce the burden on GPs / nurses by reducing the number of patients who require supervised administration and would therefore be beneficial for use in practice. In essence, this should lead to the better optimisation of NHS resources and should focus attention on meeting other local health economy needs.

Policy Drivers

Guidance available from NICE establishes:

- All women requiring contraception should be given all the necessary information and offered a choice of all methods available.
- Women should be provided with the method of contraception that is most acceptable to them, provided it is not contraindicated.
- All currently available LARC methods (intrauterine devices, the intrauterine system, injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at one year of use. Therefore the former plays a significant role in the helping reduce unintended pregnancies.

- Intrauterine devices, the intrauterine system and implants are more cost effective than the injectable contraceptives; however it is also acknowledged that there is limited use of LARC in general practice, and better guidance and training is required to allow patients to make more informed decisions.
- Sayana® Press is considered as suitable treatment option when considering initiating a patient on a parental progestogen-only contraceptive device.

South East London Area Prescribing Committee has included Sayana® Press in their formulary as a contraceptive option in females when a long acting parenteral preparation of depot medroxyprogesterone is chosen as the preferred contraceptive method of use. Prescribing can take place in Primary or Secondary care. East Kent Prescribing Group has also included Sayana Press in their Primary Care prescribing formulary as an option for long acting reversible contraception.

Equity

No impact anticipated.

Implementability

No issues identified.

References

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