PROGESTOGEN-ONLY INJECTABLE CONTRACEPTION

What's New
Sayana ® - Press/Home/PfizerPro UK

Key Points:
Sandyford no longer see patients for repeat Sayana injections. Sandyford staff facilitate self injecting on the first appointment, then issue a one year supply. However this would be dependant on the service it was commenced at. The client would be seen in a Nurse list.

Mode of Action
The primary mode of action is to prevent ovulation, supplemented by contraceptive actions at the endometrial and cervical mucus level.

Dosing Interval
The recommended dosing interval for IM DMPA (Depo-Provera®) and SC DMPA (Sayana Press®) is **13 weeks**. This is outside the product licence for Depo-Provera®.

DMPA may be administered up to 14 weeks from the last injection without the need for additional contraceptive precautions (outside product licence for Depo-Provera®).

Efficacy
Perfect use failure rate is 0.2% in the first year of use.

Injectable contraceptives are long acting reversible contraceptives. Typical use failure rates are lower than failure rates for oral contraceptives. However, injectable contraceptives are less cost-effective than the implant and intrauterine methods because users are required to return more frequently.

Administration
Shake syringe vigorously

SC DMPA
- Activate the injector according to the manufacturer's instructions (www.medicines.org.uk/emc)
- Inject into upper anterior thigh or abdomen
- Point needle downwards (towards the floor) and inject over 5-7 seconds
- Licensed for self-administration and can be offered routinely by staff trained to instruct patients
- See APPENDIX 1 procedure for self-administration in appendix

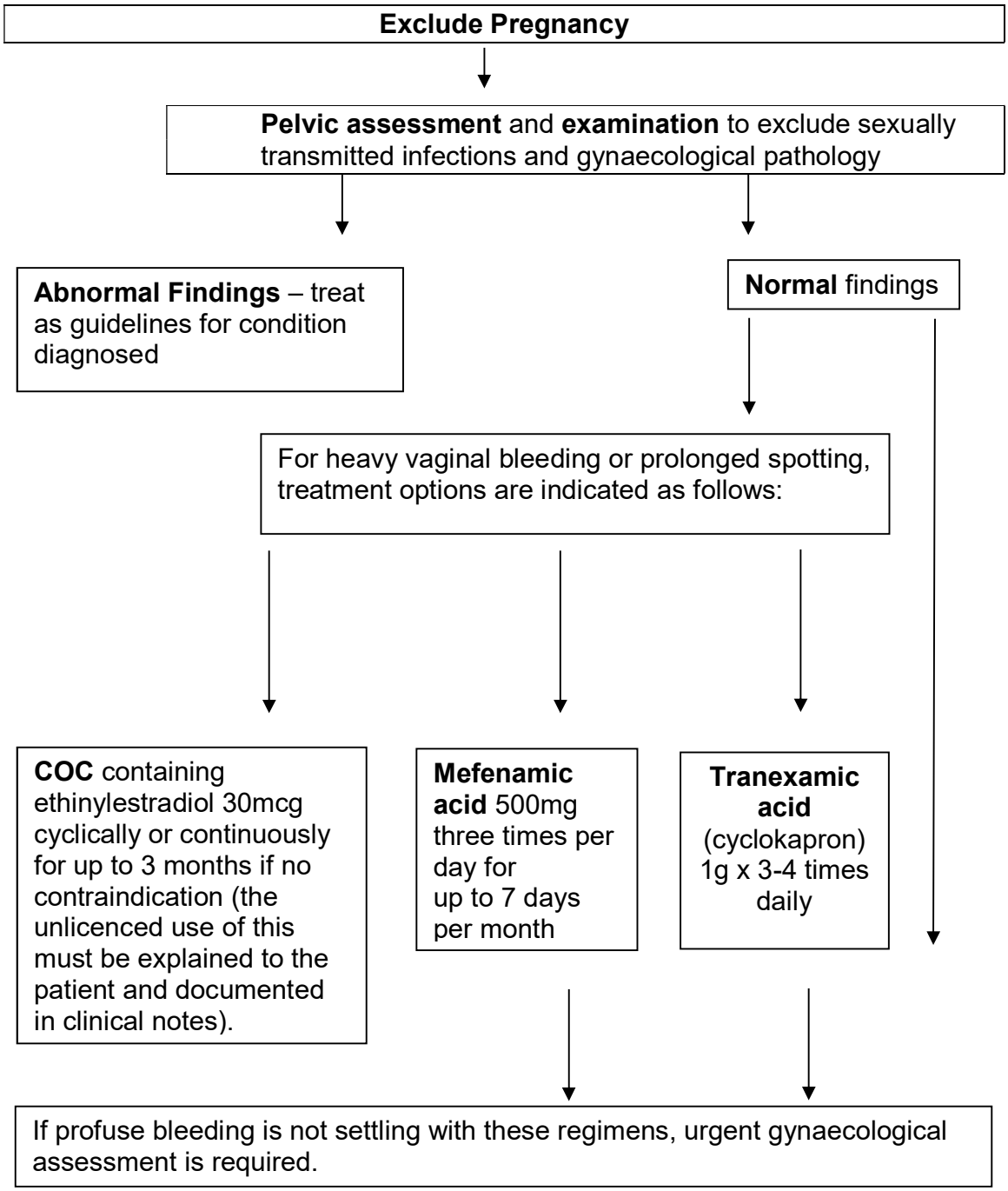
IM DMPA
- IM injection into gluteus maximus or other muscle e.g. deltoid
    - IM administration into ventrogluteal site. Is the preferred site as it reduces the risk of superficial injection and sciatic nerve injury.
    - If not yet trained in ventrogluteal injection, or if client requests, the dorsogluteal site (upper outer quadrant of buttock) or deltoid should be used.

Common Side Effects
- Change in menstrual pattern
- Delay in return of fertility. (Median time to ovulation is 6 to 7 months following the preceding injection i.e: 3 – 4 months following cessation of therapy).
- Weight gain
- Injection site reactions (more common with s.c. than i.m. administration)

Less Common Adverse Effects
- Prolonged or very heavy bleeding – history and examination must be taken to exclude gynaecology pathology (eg: pelvic, infection, miscarriage).
- Anaphylaxis
- Galactorrhoea
- Possible small increased relative risk of breast cancer and cervical cancer
- Loss of bone mineral density (see below)

Prices (As Per BNF Sep 2018**)**
Depo-Provera® £6.01
Sayana Press® £6.90

Action for Persistent Bleeding



There is no evidence that reducing the injection interval improves bleeding but the interval can be reduced to 10 weeks if the patient wishes early repeat injections.

Assessment of Client Suitability

History

• Clinical history taking and examination allow an assessment of medical eligibility for DMPA use (UK Medical Eligibility Criteria: http://mag.digitalpc.co.uk/fvx/fsrh/ukmec/2016/). In this context the history should include: relevant social and sexual history (to assess risk of sexually transmitted infections – STIs), medical, family and drug history as well as details of reproductive health and previous contraceptive use.

• Risk factors for osteoporosis should be assessed and alternative contraceptive choices discussed as appropriate.

Patient Self Administration of Sayana Press

New and existing Depo-Provera users aged between 18 and 50. They must be literate in English, have a mobile phone and give permission to be contactable by mobile phone. Also must be willing and able to self-administer Sayana Press. See GP for further supply of Sayana.

- See APPENDIX 1 procedure for self-administration

Examination

• BMI should be noted prior to commencement of injectable contraception
• Pelvic examination and cervical cytology if indicated

Documentation

•The full visit history should be completed or updated as required, including osteoporosis risk factors
• Written method information including contact number is given to client
• Prescription is recorded and dated
• Site of injection, batch number and expiry date of medication recorded
• Record date when injection is next due
• Nurse supplying where appropriate under patient group direction
• GP notified of prescription, if permission is given for correspondence

Management & Timing Of First Injection

General initiation	Ideally, first injection should occur between Days 1–5 (inclusive) of a normal menstrual cycle. No additional contraception is required. Injections may also be initiated at any other time in the menstrual cycle if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. Additional contraception (barrier method or abstinence) should be advised for 7 days after initiation. If the woman is amenorrhoeic, the clinician must be reasonably certain that the woman is not pregnant and there is no risk of conception. Additional contraception should be used for 7 days.
Post-partum	Progestogen-only injectables may be initiated up to and including Day 21 postpartum with immediate contraceptive cover. If initiated after Day 21 then condoms or abstinence is advised for 7 days. Medroxyprogesterone is safe to use during breast-feeding.
Following miscarriage or termination	Initiate on day of surgical or second part of medical abortion or immediately following miscarriage: No additional contraception is required. If started >5 days after abortion or miscarriage, additional contraception is required for 7 days.
Switching from CHC, PO implant or POP	Can be initiated immediately if method has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there has been no risk of conception. No additional contraception is needed.
Switching from PO injectable	If the woman's previous method was another injectable, she should have the injection before or at the time the next injection was due. No additional contraception is needed.
Switching from IUS	Can be initiated immediately if the LNG-IUS was used consistently and correctly or if the clinician is reasonably sure that the woman is not pregnant. As bleeding with the LNG-IUS may not reflect ovarian activity, the LNG-IUS should be continued for at least 7 days.
Switching from IUD	Can be initiated immediately if the IUD was used consistently and correctly or if the clinician is reasonably sure that the woman is not pregnant. The IUD should be continued for at least 7 days unless the

	first injection occurs between Days 1–5 (inclusive) of a normal menstrual cycle.
Switching from barrier method	Can be initiated immediately if barrier method has been used consistently and correctly or if the clinician is reasonably certain that the woman is not pregnant and that there is no risk of conception. If the woman is amenorrhoeic or it has been more than 5 days since menstrual bleeding started, additional contraception should be continued for 7 days.
Quick starting after oral EC or in other situations in which pregnancy cannot be excluded	DMPA should only be quick started in the absence of acceptable alternatives. Quick starting after Levonorgestrel EC: give DMPA immediately and advise condoms for 7 days. Quick starting after Ulipristal EC: wait for at least 5 days following EC before administering DMPA. Advise condoms for a further 7 days (12 days of condom use in total) ***patient requires a pregnancy test 3 weeks after last UPSI***

*see Appendix 2

DMPA and Bone Mineral Density

Women using DMPA contraception have a small reduction in bone mineral density (BMD) while using this method of contraception, which may be at least partly reversible on discontinuation. It is not known whether this increases the risk of osteoporosis in later life. The effect on BMD may be most marked in adolescents, who have yet to achieve their peak bone mass. For adolescent women, the MRHA recommends that DMPA is prescribed as first line contraception only after other methods have been discussed and deemed unsuitable or unacceptable.

See flow chart below for suggested management in women who wish to continue with this method of contraception for more than 2 years.

Gonadotrophin checks or oestrogen replacement are not advised.

Long Term Use Of DMPA > 2 Years

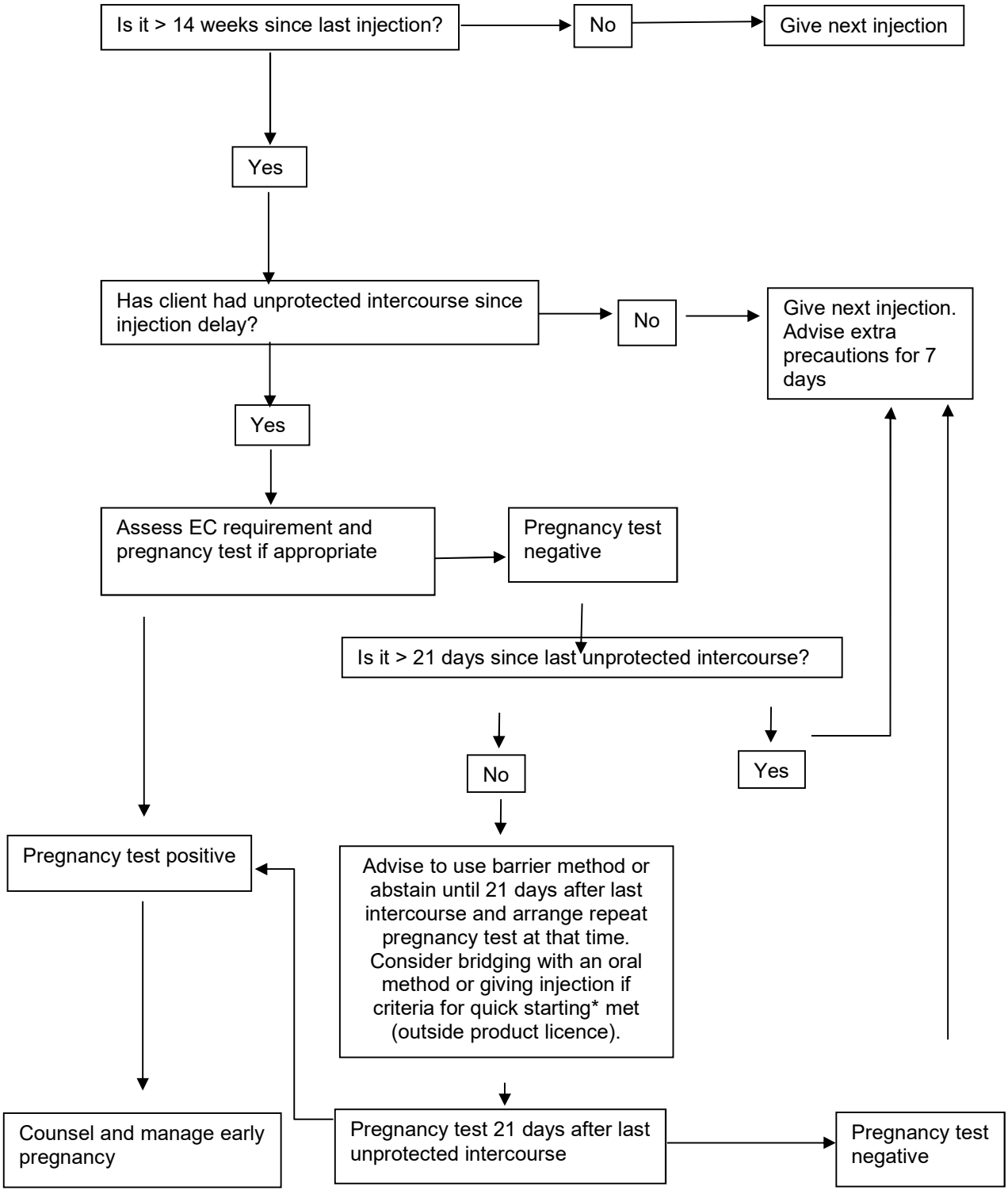
DMPA >2 years regardless of bleeding pattern

- Discuss effects of DMPA on bone density and uncertainty about risk of later osteoporosis/fracture
- Review risk factors for osteoporosis: alcohol, exercise, diet, smoking, family history, medical conditions, e.g. Crohn's or drug use, e.g. steroids
- Discuss alternative forms of contraception.
- Document discussion and client's choice in notes

Continue client contraceptive method of choice

Review indications, risk factors, alternatives every 2 years

Delayed Follow Up Visit > 13 weeks



References

FSRH. Progestogen-only injectable contraception. December 2014, amended October 2019
http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf
[accessed March 2023]

FSRH. UK Medical eligibility criteria for contraceptive use.July 2016.
http://mag.digitalpc.co.uk/fvx/fsrh/ukmec/2016/
[accessed March 2023]

FSRH. Problematic bleeding with using hormonal contraception. July 2015.
http://www.fsrh.org/pdfs/CEUGuidanceProblematicBleedingHormonalContraception.pdf
[accessed March 2023]

FSRH Drug Interactions with Hormonal Contraception January 2017
http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf
[accessed March 2023]

FSRH New Product Review. Subcutaneous medroxyprogesterone acetate. June 2013.
http://www.fsrh.org/pdfs/CEUProductReviewSayana.pdf
[accessed March 2023]

FSRH Quick Starting Contraception April 2017
http://www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf
[accessed March 2023]

APPENDIX 1

Self Administration of Sayana Press

NOT suitable for:

- Clients under 18
- Those not proficient in the English language

Consultation 1 –

A) The clinician should give the first injection while instructing the patient on its use.

B) If patient is keen to use Sayana Press, give Sayana information booklet. Give patient the video training link so that they can familiarise themselves with it: http://www.sayanaanswers.co.uk/guide-to-self-injection.

C) Send the link to them using NaSH SMS messenger and/or give them the DVD to take home.

Consultation 2 –

D) Show the patient the training video and check if they have any questions/concerns

E) Patient self administers Sayana Press under nurse supervision. If the patient wishes to continue with Sayana Press a prescription for three further doses can be dispensed.

F) Give patient a

- card on setting up text reminders,
- sharps bin and verbal instructions on use,
- date for annual review (20 mins booked appointment)

Sharps canisters should be locked and returned to Sandyford Services.

G) Set up recall on SC Sayana VD for the next three injections every 13 weeks to ensure that the patient self administers their three next injections.

H) Ask patient to set up an SMS text reminder on her mobile from Sayana Press. This involves texting SELF to 83311 with the date of her last injection e.g. SELF 27.01 (i.e. For an injection on 27th January 2016). Give her the link for setting up SMS reminder http://www.sayanaanswers.co.uk/staying-on-track.

Consultation 3 –

We no longer have an annual review. Direct this to the GP.

While rare, anaphylactic reaction is possible with both first and subsequent exposure to sayana press. It is therefore recommended that users are advised to ensure there is a competent adult present at the time of self administration who is aware that they should call for emergency help at the time of the onset of any relevant symptoms

APPENDIX 2

Check List for Quick Starting Hormonal Contraception

If risk of pregnancy cannot be reasonably excluded, the contraceptive provider should ensure that the woman is:

- Likely to continue to be at risk of pregnancy or that she has expressed a preference to begin contraception immediately.
- Aware that there is a possibility of pregnancy.
- Informed that there is a theoretical risk from foetal exposure to contraceptive hormones but most evidence indicates no harm.
- Aware that pregnancy cannot be excluded until she has had a pregnancy test no sooner than 3 weeks after the last episode of unprotected sexual intercourse.
- Provided with a pregnancy testing kit or informed of alternative options for pregnancy testing, including local and providers of free testing. The YP is given a test advice sheet and asked to follow instructions. Add to YP Virtual diary on the next Tuesday after the test is due. The Home Pregnancy Test Advice Sheet can be found on the YP Team Folder.
- Given advice on additional contraceptive precautions.
- Offered a supply of condoms or informed of local providers of condoms.
- Advised to return if there are any concerns or problems with her contraception.