Protocol for the Provision of Sub-Cutaneous Depo Medroxyprogesterone Acetate (DMPA-SQ)

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Acknowledgements

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Table of Contents

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Abbreviations

DMPA	Depo medroxyprogesterone acetate
DMPA-IM	Depo medroxyprogesterone acetate intramuscular
DMPA-SQ	Depo medroxyprogesterone acetate subcutaneous; aka DMPA-SC or “Depo sub-q”
MEC	Medical Eligibility Criteria

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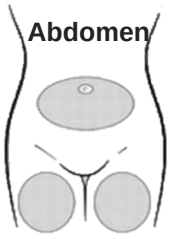
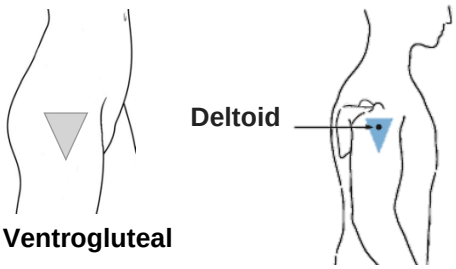
Contraceptive Injection

The contraceptive injection is also known in other medical and lay terms as Depo, Depo-Provera, DMPA, the Depo shot, the birth control shot, or just the shot. From this point forward, the intramuscular injection and subcutaneous injection will be referred to as DMPA-IM and DMPA-SQ respectively. Currently in the United States (U.S.) there is one contraceptive injection, Depo medroxyprogesterone acetate (DMPA), with two formulations. The original formulation, Depo-Provera 150 mg/1 mL, is administered by intramuscular injection while Depo-SQ Provera 104 mg/ 0.65 mL is administered by subcutaneous injection. Although the dose and mode of delivery are different, both have similar efficacy, satisfaction, and side-effects.[1-3]

Notable differences in the subcutaneous injection:

- It uses a smaller injection needle.
- Injection location is the anterior thigh or belly instead of the deep muscle of the arm or buttock.
- It is only packaged as a prefilled syringe.
- It has 30% less hormone than original dosing.
- There are slightly more local site reactions.[3]

DMPA		
Formulation	Subcutaneous (SQ)	Intramuscular (IM)
Needle	26-gauge x 3/8-inch needle	22-gauge x 1 1/2-inch needle
Dosage	104 mg / 0.65 ml	150 mg / 1 ml
Packaging	Single-dose prefilled syringe	Vial or single-dose prefilled syringe
Injection Sites	Abdomen, thigh  **Upper thigh**	Gluteal, deltoid  **Ventrogluteal**
Satisfaction	High[1-3]	High[1-4]

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Mechanism of Action

Both formulations of DMPA contain the hormone progestin and both prevent pregnancy primarily by preventing ovulation by inhibiting the release of gonadotropins. Progestins also thin the endometrial lining and thicken cervical mucus to prevent sperm from reaching the uterus.[5]

Effectiveness and Duration of Action

With typical use, DMPA is 96% effective.[5] The estimates apply to an 11 to 13-week dosing regimen. A 2019 systematic review and meta-analysis found no significant differences in pregnancies between DMPA-IM and DMPA-SQ, and they are considered equivalent in efficacy.[1]

Access to DMPA-SQ

Several studies have demonstrated patient interest, safety, and feasibility of self-administration as well as successful instruction via telehealth.[1, 2] While DMPA-SQ is not FDA-labeled for self-injection, this formulation allows patients to administer the injection at home, outside of the clinical setting. The WHO Consolidated Guideline on Self-Care Interventions for Health[6] and CDC U.S. Selected Practice Recommendations (SPR) for Contraceptive Use 2021 Update[7] include self-injection, as well as detailed guidelines regarding screening and examination prior to DMPA initiation.

Self-administration of DMPA-SQ was shown to improve continuation (up to 15%),[3] and is likely to improve access, and autonomy, while reducing barriers and patient burdens such as clinic wait times or lack of transportation. Observational studies also show patient preference for DMPA-SQ is due to less pain and fewer side effects, other than local site reactions.[3]

Improving the availability of DMPA-SQ faces several challenges. During the COVID-19 pandemic, the availability of DMPA-SQ increased somewhat, although this varied by funding source and practice setting.[8] Not all insurance companies cover DMPA-SQ, some pharmacies do not carry it, and some pharmacists will not dispense it without an additional note for clinician supervision. Expanding coverage of self-administered DMPA-SQ may expand autonomy, person-centeredness and contraceptive accessibility. Advocacy with state Medicaid programs has led to expanded coverage, including during the COVID-19 public health emergency.[2]

More healthcare providers and clinic staff need training in the instruction and provision of DMPA-SQ and many patients interested in contraceptive methods do not know about DMPA-SQ as a safe option.[8]

Candidates for Use

Use of the original form of DMPA-IM is common—especially younger patients. Approximately 15% of U.S. females ages 15-19 years who have had sexual intercourse have used it at some point. The appropriate candidate for use is a patient who wishes to prevent pregnancy or achieve non-contraceptive benefits of DMPA, such as menstrual suppression, and is eligible to use provider-administered DMPA-IM. Appropriate candidates also include adolescents.

DMPA-SQ is safe for most patients to use. DMPA-SQ is also safe to use while breast- or chest-feeding and immediately postpartum. DMPA-SQ is safe for trans and gender expansive individuals who may be using testosterone, given there are no other contraindications to progestin-only methods. There is some evidence to suggest that progesterone is more acceptable to some, as it has some androgenizing effects.[9] DMPA-SQ is a good choice for patients experienced in self-injection for other medications (such as for diabetes, heparin, gender-affirming care, IVF, or other conditions).

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Contraindications and Precautions for Injection Use

Evidence shows DMPA-IM and DMPA-SQ have similar safety profiles when used by healthy individuals. Pending further evidence, safety category classifications for DMPA-IM also apply to DMPA-SQ.

Box 1: CDC U.S. Medical Eligibility Criteria (MEC) for Contraceptive Use[10] for DMPA-SQ

Category 4 – Unacceptable health risk, absolute contraindication

Category 3 – Theoretical/proven risk generally outweigh advantages

Category 2 – Advantages generally outweigh the theoretical/proven risks

Category 1 – No Restriction

Absolute Contraindications (US MEC Category 4)

- Current breast cancer

Relative Contraindications (US MEC Category 3)

- Past breast cancer and no evidence of current disease for 5 years
- Liver disease
    - Severe decompensated cirrhosis
    - Liver tumors
        - Benign
        - Hepatocellular adenoma
        - Malignant (hepatoma)
- Diabetes with nephropathy/retinopathy/neuropathy
- Diabetes with other vascular disease or diabetes of >20 years' duration
- Hypertension with
    - Systolic ≥160 or diastolic ≥100
    - Vascular disease
- Ischemic heart disease (current and history of)
- Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)
- Rheumatoid Arthritis a) On immunosuppressive therapy
- Stroke (history of CVA)
- SLE (systemic lupus erythematosus)
    - Positive (or unknown) antiphospholipid antibodies
    - Initiation with Severe thrombocytopenia
- Unexplained vaginal bleeding (suspicious for serious condition) before evaluation

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Initiating DMPA-SQ

Counseling Prior to Start of DMPA-SQ

Following patient-centered counseling based on method priorities, counseling should include information on the mechanism of action, mode of administration, effectiveness, advantages, disadvantages, side effects and potential bleeding changes. Appropriate counseling, selection, and follow-up should improve client satisfaction with the method.[11] Consider sensitivity to individuals in recovery from substance use who may find needles triggering and may desire counseling of alternate methods.

Potential barriers to self-administration include fear of needles and fear of incorrect administration.[11] Therefore, education and training in self-administration is important for patients to gain confidence in dosing. Education and training can be performed in-person or via a telemedicine visit, and should include review of supplies, self-administration instructions, and safe needle disposal instructions for patients.

How to Give Yourself a DMPA-SQ Injection

Supplies needed for self-administration include:

- Alcohol pads
- Prefilled syringe with DMPA-SQ 104 mg/ 0.65 mL
- Sharps container or other ***safe disposal instructions*** for used needles

Several organizations have developed educational materials for step-by-step administration of DMPA-SQ. The medication comes with specific instructions on how to administer it. Providers can share website addresses for instructions, video links, QR codes, or handouts for these various educational materials with patients. This video[12] provides patients education on how to prepare, location of body to prep, and how to self-administer the subcutaneous injection.

Instructions:

1) Always start by washing your hands.
2) Remove the syringe from the package and shake it for about one minute to make sure the medication is well mixed. Hold the needle pointing up and tap the syringe to shake any air bubbles to the top. Push the syringe until all the air bubbles are out.
3) Pick the injection site: either upper thigh or belly.
4) Wipe the skin with an alcohol pad and wait for the area to dry.
5) Take the cap off the needle and hold the syringe in your dominant hand.
6) Grab the skin around the injection site with your other hand. Insert the small needle all the way into this skin at about a 45-degree angle. This may feel sharp but will be less painful than a DMPA-IM injection.
7) Press the syringe all the way in, and then keep the needle in place while you count to 5.
8) Remove the needle and dispose of it in a sharps container.
9) Apply pressure to the spot.

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10) Determine the date for the next injection which should take place every 13 weeks. Contraceptive reminders can help patients remember these important dates; for example, www.bedsider.org/reminders.[13]

11) DMPA-SQ can be stored at room temperature.

Safe needle disposal*:* Needles may be placed in a strong plastic container. What patients do to safely dispose of such a container depends on the U.S. state. See this resource for information for each state: https://safeneedledisposal.org.[14]

Testing Prior to Start of Medication

Healthy patients do not require examination or tests before initiation of DMPA-SQ. A comprehensive medical history should be conducted prior to initiation of DMPA-SQ to determine they are appropriate candidates based on the U.S. MEC. A baseline weight and BMI measurement may be useful for long term monitoring of DMPA-SQ users.[15]

Initiation

The first DMPA-SQ injection can be given at any time if it is reasonably certain that the patient is not pregnant (See Box 2).[15] Repeat DMPA-SQ injections should be given every 13 weeks or every 3 months.

After emergency contraception with ulipristal acetate, consider delaying initiation of DMPA for 5 days (as it decreases efficacy), weighing the risk of not initiating DMPA.

Box 2: How to be reasonably certain that a patient is not pregnant

A healthcare provider can be reasonably certain that a patient is not pregnant if they have no symptoms or signs of pregnancy and meets any one of the following criteria:

- Is < 7 days after the start of normal menses
- Has not had sexual intercourse since the start of the last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is < 7 days after spontaneous or induced abortion
- Is within 4 weeks postpartum

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Special Considerations

Early Injection

Repeat DMPA-SQ injections can be given early as necessary when a patient is unable to return during the recommended timeframe.[15]

Late Injection

- If up to 2 weeks late (15 weeks from last injection) for repeat DMPA-SQ, injection can be given without requiring additional contraceptive protection.
- If >2 weeks late (>15 weeks from the last injection) for repeat DMPA-SQ:
  - Injection can be given if it is reasonably certain that they are not pregnant (See Box 2).[15]
  - Patient should abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
- Consider the use of emergency contraception (EC) as appropriate. As mentioned, after EC with ulipristal acetate, consider delaying initiation of DMPA for 5 days (as it decreases efficacy), weighing the risk of not initiating DMPA.

Need for Back-Up Contraception

If DMPA-SQ is started within the first 7 days since menstrual bleeding started, no additional contraceptive protection is needed.

If DMPA is started >7 days since menstrual bleeding started, the patient should abstain from receptive sexual intercourse or use additional contraceptive protection for the next 7 days.

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Follow-Up After DMPA-SQ Initiation

No routine follow-up visit is required after DMPA-SQ initiation.[15] However, specific patients may benefit from more frequent follow-up visits, particularly adolescents, those benefiting from further instruction or those with medical conditions requiring follow-up. Patients may return at any time to discuss side effects, concerns, or desires for other methods of contraception.

At follow-up visits, assess the patient's satisfaction with contraception method and address any weight changes, particularly if the patient is concerned that weight changes may be associated with DMPA. Also assess any changes in health status that could alter safety of continuation (U.S. MEC category).

Box 3: A patient should be seen and evaluated as soon as possible if any of the following occur:

- Heavy vaginal bleeding or bleeding that lasts more than 14 days
- Concern about possible pregnancy
- Onset or worsening of migraine or severe headaches
- Onset or worsening of depression
- Any concerning symptom occurring with the onset or continued use of DMPA-SQ

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Changes Anticipated with Injection Use

Menstrual Changes

Menstrual changes are seen in patients using DMPA and include irregular bleeding, spotting (lasting 7 or more days during the first several months of use) and amenorrhea. Approximately half of all people using DMPA for a year experience amenorrhea. Menstrual changes are the most common cause for dissatisfaction and discontinuation of use. These bleeding irregularities are generally not harmful and may decrease with continued DMPA use. So proper counseling, patient self-selection, and follow-up are essential and can improve patient satisfaction.

Amenorrhea

Amenorrhea does not require any medical treatment. Seventy-three (73%) percent of DMPA-SQ users between 25-35 years reported amenorrhea at 12 months compared to 53% of those under age 25.[16] Provide reassurance.

Unless unacceptable to patients, amenorrhea does not require any medical treatment. Provide reassurance as appropriate. If a patient's regular bleeding pattern changes abruptly to amenorrhea, consider ruling out pregnancy if clinically indicated. If amenorrhea persists and patients find it unacceptable, counsel them and offer an alternative contraceptive method.

Unscheduled Spotting or Light Bleeding

If patients experience unscheduled or light bleeding, consider underlying gynecological problems such as:

- Pregnancy
- New medication interactions
- A sexually transmitted infection (STI)
- New pathologic uterine conditions (e.g., polyps or fibroids)

If an underlying gynecological problem is found, treat the condition or refer for care as needed. DMPA should be discontinued if pregnancy is diagnosed. A patient may continue DMPA as long as the condition is not a new contraindication.

If an underlying gynecologic problem is not found and the patient wants treatment, a short course of NSAIDs can be dosed for 5–7 days.[15]

If unscheduled spotting or light bleeding persists and patients find it unacceptable, counsel them and offer an alternative contraceptive method.

Heavy or Prolonged Bleeding

Consider underlying gynecological problems such as:

- New medication interactions
- A sexually transmitted infection (STI)
- Pregnancy
- New pathologic uterine conditions (e.g., polyps or fibroids)

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If an underlying gynecological problem is found, treat the condition or refer for care. DMPA should be discontinued if pregnancy is diagnosed. Provider can determine if DMPA can be continued based on treatment plan for other underlying gynecological diagnoses.

If an underlying gynecologic problem is not found and the patient wants treatment, the following treatment options during days of bleeding can be considered:

- NSAIDs for short-term treatment (5-7 days)
- Hormonal treatment (if medically eligible) with low-dose combined oral contraceptives (COC) or estrogen for short-term treatment (10–20 days)

If heavy or prolonged bleeding persists and patients find it unacceptable, counsel them and offer an alternative contraceptive method.

Weight Changes

Weight gain is cited as one of the most common reasons for DMPA discontinuation.[17, 18] Multiple factors appear to play a role in weight gain over time and should be considered when counseling about this side effect, as observational study results have been varied and inconsistent.

Two systematic reviews note that the only randomized trial found no association of DMPA and weight gain and that other reports were inconsistent as to whether DMPA was associated with changes in dietary habits or behavior leading to weight gain.[17, 18] An older systematic review observed that DMPA users who gained >5 percent of baseline body weight within six months of starting DMPA appeared to be at increased risk of weight gain over the following two to three years.[19, 20] Additionally one study showed DMPA-associated weight gain was due to an increase in fat mass and not lean mass,[21] but behavioral mechanisms remains unclear.

In terms of guidance, monitoring weight remotely or in-office may help to support patients concerned about weight changes with DMPA use, and counsel patients that individuals with a tendency to gain weight may struggle with weight gain while using DMPA. Additionally, those with rapid and undesired weight gain in the first few months of DMPA use may be counseled to consider other methods If the patient finds this bothersome.

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Other Provider Resources

- Innovating Education in Reproductive Health: "This is How I Teach: Self-Injection DMPA-SC" (narrated by Dr. Karlin)
- RHAP Quick Start Algorithm

Patient References / Resources

- Fact sheet for DMPA-SC self-injection, in multiple languages including English, Spanish, Vietnamese, Hindi, Simple and Traditional Chinese (RHAP)
- English Factsheet: DMPA-SC: The do it-yourself birth control shot (Bedsider.org)
- English video about DMPA-SC self-injection (Planned Parenthood)
- English patient guidelines for DMPA-SC self-injection (Planned Parenthood)
- Spanish video about DMPA-SC self-injection (Planned Parenthood)
- Spanish patient guidelines for DMPA-SC self-injection (Planned Parenthood)
- Contraceptive Pearl: Expanding Access to the Self-Administered Contraceptive Injection (RHAP, July 2020)
- Contraceptive Pearl: Contraception During COVID-19: Self-Administered Progestin Injection: Depo SubQ (RHAP, April 2020)
- English video: How to perform a subcutaneous injection using a prefilled syringe (RHEUMinfo)
- Safe Needle Disposal
- Patient label with Instructions for Use of Depo-SubQ Provera (Pfizer)

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