CLINICAL TEMPLATE PROTOCOL

**DMPA SQ and Self-Administration Procedures**

*This template protocol is intended to assist family planning providers in developing local protocols for implementing self-administration of depot medroxyprogesterone acetate subcutaneously (DMPA SQ) in family planning settings.*

A clinical protocol is a site-specific policy for the provision of high-quality health care to patients. It clarifies the scope of care that can be provided by clinicians and care team members, consistent with state regulations. Clinical protocols from one organization should never be adopted intact by another organization without first revising them, since these protocols will not include an accurate description of the adopting organization’s policies and procedures nor will they account for other organizational considerations.

Refer to NFPRHA’s resource, **Developing Clinical Protocols for Family Planning Services,** for more information on clinical protocols, including best practices for development.

**HOW TO USE A NFPRHA TEMPLATE PROTOCOL**

Each NFPRHA template protocol is written with the understanding that several decision points must be addressed by an organization before the protocol is ready for use. When an organization decides to use a NFPRHA template protocol, the author will tailor the contents to their own organization and create a draft local protocol. It is recommended that, before organization-wide implementation, a draft of the revised template be reviewed and tested by clinicians to allow them to weigh in on accuracy, completeness, and usability.

**REVIEW DECISION POINTS**

Decision points are listed in **[blue]** throughout the template document. It is expected that the person(s) using the template protocol as a starting point will include the appropriate option that reflects their organization’s current practices. If the organization has policies, procedures, or practices that are not listed as an option, they should be described in detail and inserted into the draft local protocol. When formatting the draft local protocol, the options that do not apply to the organization should be deleted.

**TEST WITH CLINICIANS**

Once a template protocol is used to create a draft local protocol, this document should be reviewed and edited by select clinicians who ultimately will provide care to patients under the guidance of the final version of the local protocol. Not only will this serve as a “reality test” of whether the draft local protocol accurately reflects what currently is practiced within the organization; in addition, it will give clinicians an opportunity to provide feedback regarding new policies and procedures that may have been included in the draft local protocol. In this way, it is much more likely that all clinicians will have a sense of “buy-in” to the new local protocol once implemented.

**Introduction**

[Name of health center or system] has implemented depot medroxyprogesterone acetate subcutaneously (DMPA SQ) for self-administration by patients outside of the health center. This template protocol does not address administering DMPA on-site, nor does it include guidance related to types of modalities that may be used (e.g., telehealth) to capture relevant information or procedures for communication with patients remotely. [If your health center or system has a protocol for DMPA IM and/or on-site administration of DMPA SQ, please list titles and locations here. Alternatively, text within this template protocol can be inserted into your health center or system’s existing DMPA protocol or attached as an appendix. For a full detailed description of the method and related data, please see the prescribing information at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=549>.

**Background**

There is a growing need to identify opportunities and develop plans to offer alternative options for expanding clinical care beyond the traditional health center setting. Environmental challenges such as natural disasters and the most recent COVID-19 public health emergency have created an opportunity for use of alternative delivery models for ensuring patient access to contraception.[[1]](#footnote-1) Effective [date], [Name of health center or system] offers DMPA SQ to patients for self-administration as a strategy to reduce the need for in-person visits and remove barriers that patients may encounter when accessing the initiation of this method and reinjections.

DMPA SQ was approved by the Food & Drug Administration (FDA) in 2004. Current labeling states, "Depo SQ Provera 104 is only for subcutaneous administration and is only to be administered by a healthcare professional.”[[2]](#footnote-2) Consequently, prescription of DMPA SQ to a patient for self-administration is considered an “off-label” use. However, several studies have demonstrated the safety and feasibility of self-administered DMPA SQ.[[3]](#footnote-3),[[4]](#footnote-4)

**Product Information and Use**

**Candidates for DMPA SQ**

DMPA SQ can be used by patients that are new to DMPA or by patients who currently receive DMPA 150 mg IM and want to switch to this delivery route after learning how to self-administer. Patients who have previous experience with self-administration of other injected drugs (such as insulin or drugs for multiple sclerosis) are good candidates for self-administered DMPA SQ. Providers should use their clinical judgement to determine whether this method of delivery is appropriate for a specific patient and document this decision in the patient’s medical record.

**Specific Populations**

* DMPA SQ can be used by women of all ages, including adolescents.
* Body weight: No dosage adjustment of DMPA SQ is necessary based on body weight.

**Typical Use**

Approximately 4 out of 100 women will become pregnant in the first year of use of DMPA SQ with typical use.[[5]](#footnote-5)

**Contraindications**

The contraindications and precautions for DMPA SQ are the same DMPA 150 mg IM. The Centers for Disease Control and Prevention’s (CDC) Medical Eligibility Criteria for Contraceptive Use ([US MEC, 2016](https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm)) lists DMPA categorization as follows:[[6]](#footnote-6),[[7]](#footnote-7)

* Category 4: Breast cancer treated within the past 5 years
* Category 3:
	+ Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)
	+ Systolic ≥160 mm Hg or diastolic ≥100 mm Hg
	+ Hypertension with vascular disease
	+ Current and history of ischemic heart disease
	+ History of stroke
	+ Systemic lupus erythematosus:
		- Positive (or unknown) antiphospholipid antibodies (initiation and continuation of the method)
		- Severe thrombocytopenia (initiation of the method only; continuation of DMPA is Category 2)
	+ Unexplained vaginal bleeding (suspicious for serious condition before evaluation)
	+ Breast cancer in the past; no evidence of recurrent disease for 5 years
	+ Diabetes with nephropathy, retinopathy, or neuropathy or other vascular disease
	+ Diabetes of >20 years’ duration
	+ Cirrhosis; severe, decompensated
	+ History of benign or malignant liver tumor

**How Supplied**

DMPA SQ (medroxyprogesterone acetate injectable suspension 104 mg/0.65 mL) is available as a pre-filled syringe, packaged with a 26- gauge x 3/8 inch Terumo® Surguard™ needle in the following presentation: NDC 0009-4709-13 0.65 mL single-use, disposable syringe. Store at controlled room temperature 20º to 25º C (68º to 77ºF) (see USP). Prescription only, with ordering amount of 103 units.[[8]](#footnote-8)

**Procedures for Use of DMPA SQ**

The following information addresses protocols for initiation of DMPA SQ per the current U.S. Selected Practice Recommendations (US SPR) for Contraceptive Use, 2016 and the U.S. Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. [Note: As appliable, include information about whether RNs can furnish DMPA SQ for self-administration under this protocol and based on standing orders].

**Medical History for Initiation**

Beyond a routine medical history and contraceptive counseling, discussion with the patient should be directed at ruling out the possibility of pregnancy and assessing eligibility for and safe use of DMPA SQ. In particular, the patient’s willingness to learn self-administration technique, prior experience of pain with office injections, and a history of vaso-vagal syncope with injections must be included.

**Examinations and Tests Needed Before Initiation**

No special physical assessments or tests are needed before initiation of DMPA SQ. A baseline weight measurement (performed at home by the patient and disclosed to her clinician) will help with monitoring patients over time for those patients concerned about weight gain. [Health center or system should determine the minimum set of criteria necessary to determine how a clinician may decide if and when to require a baseline weight and body mass index (BMI), as these decisions have implications for integration with remote health care delivery models (e.g., telehealth), and reference here]. Screening for hypertension before initiation of DMPA SQ is not necessary.

**Counseling Points**

Counsel patients on use, potential barriers to consistent and correct use, evidence-based side effects, risks, and potential changes in bleeding patterns during use. [If your health center or system has a clinical protocol related to contraceptive counseling, please list title and location here]. Amenorrhea and unscheduled spotting or light bleeding are common side effects with DMPA SQ use, while heavy or prolonged bleeding is uncommon. [Health center or system should consider adding information related to managing common side effects, specifically the abnormal bleeding profile associated with this contraceptive method. Side effects may contribute to discontinuation of the method, so clinicians should know how to appropriately counsel patients on management and treatment options.] These bleeding irregularities generally are not harmful and might decrease with continued use.

**Initiation of DMPA SQ**

##### *Timing*

* The first DMPA SQ injection can be given at any time if it is reasonably certain that the patient is not pregnant. [If the health center or system has an algorithm for initiating hormonal contraception included in another clinical protocol, please list title and location here.]

##### Need for back-up contraception:

* + If started within the first 7 days of the menstrual period, no additional contraceptive protection is needed.
	+ If started >7 days since menstrual bleeding began, the patient needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

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##### *Switching from Another Contraceptive Method*

* Timing: The first DMPA SQ injection can be given immediately if it is reasonably certain that the patient is not pregnant. Waiting for her next menstrual period is unnecessary.
* Need for back-up contraception: If it has been >7 days since menstrual bleeding started, the patient needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
* Switching from another method:

| **Previous Method** | **Timing** |
| --- | --- |
| Combined hormonal contraceptives | Administer the first injection of DMPA SQ within seven days after the last day of using the combined hormonal contraceptive method (i.e., within seven days after taking the last active pill).  |
| Contraceptive implant | Administer the first injection of DMPA SQ on the day of implant removal. |
| Contraceptive vaginal ring or transdermal system | Administer the first injection of DMPA SQ on the day the patient would have inserted the next ring or applied the next transdermal system |
| Intrauterine device (IUD) | If the patient has had sexual intercourse since the start of menses and it has been more than 5 days since menstrual bleeding began, it is possible that residual sperm might be in the genital tract, which could lead to fertilization if ovulation occurs. [Health center or system may consider including any of the following options:* Advise the patient to retain the IUD for at least 7 days after the injection and return for IUD removal.
* Advise the patient to abstain from sexual intercourse or use barrier contraception for 7 days before removing the IUD and switching to the new method.
* If the patient cannot return for IUD removal and has not abstained from sexual intercourse or used barrier contraception for 7 days, advise the patient to use ECPs (with the exception of ulipristal acetate, or UPA) at the time of IUD removal.]
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*Special Patient Considerations for Initiation:* [Note: There may be a need to separate and expand this section depending on the health center or system's patient population].

|  |  |  |
| --- | --- | --- |
| **Population** | **1st Injection** | **Need for Backup**  |
| Amenorrhea (not postpartum) | The first DMPA SQ injection can be given at any time if it is reasonably certain that the patient is not pregnant | 7 days |
| Postpartum (Breast feeding) | The first DMPA injection can be given at any time, including immediately postpartum (US MEC Category 2 if <1 month postpartum and US MEC Category 1 if ≥1 month postpartum) if it is reasonably certain that the patient is not pregnant | If < 6 months postpartum: no backup needed ≥ 21 days postpartum and has not experienced return of menstrual cycle: 7 daysIf menstrual cycles have returned and it has been >7 days since menstrual bleeding started: 7 days |
| Postpartum (Not breastfeeding) | The first DMPA SQ injection can be given at any time, including immediately postpartum (US MEC Category 1) if it is reasonably certain that the patient is not pregnant | If a patient is <21 days postpartum, no additional contraceptive protection is needed≥ 21 days postpartum and has not experienced return of menstrual cycle: 7 daysIf menstrual cycles have returned and it has been >7 days since menstrual bleeding started: 7 days |
| Post Abortion (Spontaneous or Induced) | The first DMPA SQ injection can be given within the first 7 days, including immediately after the abortion (US MEC Category 1) | 7 days unless the injection is given at the time of a surgical abortion |

In situations in which the health care provider cannot determine the patient’s pregnancy status, the benefits of starting DMPA SQ may outweigh risk; therefore, starting DMPA SQ should be considered at any time, with a follow-up pregnancy test in 2-4 weeks.[[9]](#footnote-9) If the patient needs to use a back-up method when switching to DMPA SQ from another contraceptive method, consider continuing her previous method for 7 days after the DMPA SQ injection.

**Reinjection interval**

* The package insert for Depo SQ Provera 104 states that the recommended injection interval is every 12-14 weeks.
* The DMPA reinjection interval recommended in the US SPR states that, while repeat injections should be given every 13 weeks, a late DMPA injection can be given up to two weeks late (15 weeks from the last injection) without requiring additional contraceptive protection. The extended “grace period” of DMPA is based on a systematic review published in 2009 which included only DMPA IM.[[10]](#footnote-10) However, studies among women in Africa suggest that the same 15-week limit also applies to DMPA SQ.[[11]](#footnote-11)
* Late injections (adapted from US SPR):
	+ If more than two weeks late for a repeat DMPA injection (more than fifteen weeks), the patient can have the injection if it is reasonably certain that they are not pregnant. The patient needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven days. The patient might consider the use of levonorgestrel emergency contraception (EC), but not UPA EC.
	+ Suggest that patients set reminders for themselves about dates for reinjection. Alternatively, health centers can set up telephone visits to remind and support patients during self-administration, if desired.

**Patient education in injection technique**

* Ideally, patients starting this method should receive instruction in self-administration technique in-person or during a synchronous audio/video telehealth visit. However, if this is not possible, the patient should be provided with educational materials that include step-by-step instructions for self-administration, as well as guidance on the proper disposal of needles.
* Simplified step-by-step instructions:
1. Wash hands.
2. Remove syringe from package and shake it one minute until mixed.
3. Hold needle pointing up and tap syringe to shake air bubbles to top
4. Push syringe until air bubbles are out.
5. Choose injection site (in abdomen or anterior thigh), wipe with alcohol pad, and let area dry.
6. Take cap off needle and hold syringe in dominant hand.
7. Grab skin around injection site with non-dominant hand and insert needle all the way into skin at 45-degree angle.
8. Press syringe all the way in and keep needle in place while counting to five.
9. Remove needle and dispose of into a sharps disposal container.
10. Apply light pressure to prevent bleeding without massaging.

**Patient Resources**

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| **Resource**  | **Website**  |
| Reproductive Health Access Project, Depo SubQ User Guide (PDF)  | [www.reproductiveaccess.org/resource/de po-subq-user-guide/](http://www.reproductiveaccess.org/resource/depo-subq-user-guide/)  |
| RheumInfo, How to Give a Subcutaneous Injection Using a Pre-filled Syringe (video)  | [www.youtube.com/watch?v=arcr1wjun6c](http://www.youtube.com/watch?v=arcr1wjun6c)   |
| SafeNeedleDisposal.org, Educational Materials  | [safeneedledisposal.org/resourcecenter/online-brochures/](https://safeneedledisposal.org/resource-center/online-brochures/)  |
| Bedsider Provider Perspectives, Depo SubQ:  | [www.bedsider.org/features/789-deposubq-the-do-it-yourself-birth-control-shot](http://www.bedsider.org/features/789-depo-subq-the-do-it-yourself-birth-control-shot)  |
| PATH, DMPA SQ Self-Injection Resources (webpage)  | [www.path.org/programs/reproductivehealth/dmpa-sc-self-injection/](http://www.path.org/programs/reproductive-health/dmpa-sc-self-injection/)  |
| Pfizer, Depo SQ Provera 104 Prescribing Information (webpage)  | [www.pfizermedicalinformation.com/enus/depo-subq-provera-104#S3](http://www.pfizermedicalinformation.com/en-us/depo-subq-provera-104#S3)  |

Patients may also benefit from receiving additional resources to help them remember when to administer their follow-up injections, such as:

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| Resource  | Website  |
| Bedsider, *Birth Control Reminder App*  | [www.bedsider.org/reminders](http://www.bedsider.org/reminders)  |
| Reproductive Health Access Project, *Progestin Injection 15-week Cycle Calendar*  | [www.reproductiveaccess.org/wpcontent/uploads/2016/04/Progestin-Injection-](http://www.reproductiveaccess.org/wp-content/uploads/2016/04/Progestin-Injection-Perpetual-calendar-15-week-cycle.pdf)[Perpetual-calendar-15-week-cycle.pdf](http://www.reproductiveaccess.org/wp-content/uploads/2016/04/Progestin-Injection-Perpetual-calendar-15-week-cycle.pdf)  |

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| Sample Script for Staff to Assess DMPA SQ Self-Administration Interest[[12]](#footnote-12) |
| [Health center or system may find the following script useful when providing outreach to patients, if applicable. Staff who are familiar with providing counseling and education about contraception can utilize this sample script to initiate the calls to patients who are candidates for DMPA SQ].1. Introduce yourself and explain why you are calling:Hi, my name is (your name), the [title] at [health center or system name]. I am calling because we are looking at ways to make accessing your birth control method more convenient for you. [Can add: Due to COVID-19 public health emergency or other related reason, if applicable)].2. I am reaching out to current Depo users. * Are you still using the birth control shot (i.e., Depo) as your birth control method? (Y/N)
* Are you satisfied with the method? (Y/N)
* If answers “no” to any of the above questions, ask why and provide appropriate counseling.
* If the answer is “yes,” proceed to Question 3.

3. Great, glad to hear you are satisfied with your method. You may be surprised to learn that it's possible to administer your birth control shot in the comfort of your home. Many patients really like this way of receiving their birth control shot.This birth control shot, which also is referred to as Depo SQ, is a little different than your current shot. It contains a lesser amount of the hormone that stops you from getting pregnant and uses a smaller needle for an easier injection. It hurts less than the injection(s) you received in the past but works exactly the same way. 4. Use of this method would require you to inject yourself. Is that something that would interest you? Would you be comfortable with that? * If no and they want to continue with DMPA IM, arrange for the patient to receive their next injection at the health center.
* If yes, refer the patient to a clinician for a visit [if applicable] to discuss use and risks, prescribe the method, and arrange how the patient will receive the method including instructions of injection procedure (e.g., health center, pharmacy, mailing to the address of choice).

5. That’s great, I am happy to hear you are interested in using this type of birth control shot. While you wait for your appointment, let me share some resources with you that you can review on your own (e.g., [www.bedsider.com](http://www.bedsider.com)). [Determine the list of resources and websites to which interested patients will be referred].  |

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| Quick Reference Guide for Dispensing Self-Administered DMPA SQ |
| **What is it?*** DMPA SQ injectable suspension (104 mg/0.65 mL) in a single dose prefilled syringe package with a 26-guage X ⅜” Terumo SurGuard™ needle.

**Why offer it to patients?** * It’s available to be administered at home.
* There is less discomfort - less hormone amount and smaller needle.
* Requires a total of 4 injections per year.
* Eliminates need to come to the health center for injections, which may present logistical challenges for the patient.
* The product is available for pickup or delivery (e.g., health center, pharmacy, or via mail).
* It’s cost effective and convenient.

**Who’s eligible?*** DMPA SQ is reversible and can be used by women of all ages, including adolescents.

**What are the contraindications?*** Active thrombophlebitis, or current or history of thromboembolic disorders, or cerebral vascular disease
* Known, suspected, or past malignancy of the breast
* Significant liver disease
* Known hypersensitivity to medroxyprogesterone acetate or any of the ingredients in DMPA SQ
* Undiagnosed vaginal bleeding

 **What about…?*** Weight Issues - Obese women can use (US MEC Category 1) or generally can use (US MEC Category 2) DMPA SQ; therefore, screening for obesity is not necessary for safe initiation.
* High Blood Pressure - Women with hypertension generally can use Depo SQ (US MEC Category 2), with the exception of women with severe hypertension or vascular disease, who generally should not use DMPA SQ (US MEC Category 3). Screening for hypertension before initiation of DMPA SQ is not necessary.

**What should you tell patients?*** Discuss common side effects including the possibility of experiencing irregular bleeding, as well as low bone density warnings (per the prescribing information).
* Recommend patients to take over-the-counter calcium and vitamin D supplements.
* Explain instructions on use and storage of the method:
	+ Store at room temperature 20° C to 25° C (68° F to 77°F). Do not refrigerate.
	+ How to “Quick Start” method and use of backup method, if applicable.
	+ Procedures for injection, prepping the area with alcohol, and prepping the syringe for the subcutaneous injection. May reference videos or injection diagram images.
	+ Areas for injection - anterior thighs and abdomen.
* Resources/information for disposing of used syringes.
* Need for repeat injection every 13 weeks.
* Use condoms for dual protection against sexually transmitted infections (STI) and HIV.
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This document was prepared by the National Family Planning & Reproductive Health Association (NFPRHA). It is intended for informational purposes and does not constitute legal or medical advice or NFPRHA’s endorsement of a specific product.

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1. Birthe Dinesen et al., “Personalized Telehealth in the Future: A Global Research Agenda,” in *Journal of Medical Internet Research* 18, no. 3 (2016). [↑](#footnote-ref-1)
2. Pfizer. Patient Information DEPO-SUBQ Provera 104. (December 2019). [↑](#footnote-ref-2)
3. Office of the Commissioner. “Understanding Unapproved Use of Approved Drugs ‘Off Label’” U.S. Food and Drug Administration (2018). [↑](#footnote-ref-3)
4. American College of Obstetricians and Gynecologists’ Committee on Gynecologic Practice, “Over-the-Counter Access to Hormonal Contraception,” *Obstetrics & Gynecology* 134, no. 4 (2019). [↑](#footnote-ref-4)
5. National Family Planning & Reproductive Health Association (NFPRHA). Reproductive Resource Guide: Self-Administration of Injectable Contraception. (Updated April 13, 2020). [↑](#footnote-ref-5)
6. Naomi K. Tepper et al., Update to U.S. Medical Eligibility Criteria for Contraceptive Use, 2016: Updated Recommendations for the Use of Contraception Among Women at High Risk for HIV Infection. *MMWR Morb Mortal Wkly Rep* 69 (2020): 405-410. [↑](#footnote-ref-6)
7. 4 = A condition that represents an unacceptable health risk if the contraceptive method is used; 3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method. The use of the method usually is not recommended unless other more appropriate methods are not available or acceptable; however, the risk of the method is less than pregnancy and it can be used. [↑](#footnote-ref-7)
8. NFPRHA. Reproductive Resource Guide. (2020) [↑](#footnote-ref-8)
9. Kathryn M. Curtis et al. U.S. Selected Practice Recommendations for Contraceptive Use, 2016. *MMWR Recomm Rep* (2016); 65 (No. RR-4):19. DOI: <http://dx.doi.org/10.15585/mmwr.rr6504a1>. [↑](#footnote-ref-9)
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12. Micah Katz et al. An implementation project to expand access to self-administered depot medroxyprogesterone(DMPA). *Contraception* (In press). DOI:https://doi.org/10.1016/j.contraception.2020. [↑](#footnote-ref-12)