



This template protocol is intended to assist clinical providers in developing local protocols for implementing self-administration of depot medroxyprogesterone acetate subcutaneously (DMPA SC) in family planning settings. If your organization decides to use this template protocol, the author will tailor the contents to their own organization and create a local protocol. Decision points are listed as NOTE alerts 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.

Introduction

Name of Setting

_____ has implemented depot medroxyprogesterone acetate subcutaneously (DMPA SC) for administration by patients outside of the health center. This template protocol does not address administering DMPA on-site (IM or SC), 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.

NOTE: If your health center or system has a protocol for DMPA IM and/or on-site administration of DMPA SC, 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

DMPA SC was approved by the Food & Drug Administration (FDA) in 2004. Current labeling states that "Depo SC Provera 104 is only for subcutaneous administration and is only to be administered by a healthcare professional."¹ Consequently, prescription of DMPA SC to a patient for self-administration is considered "off-label" use.^{2,3} However, several studies have demonstrated the safety and feasibility of self-administered DMPA SC in the US.^{4,5 6,7}

Candidates for DMPA SC

DMPA SC 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.

Specific Populations

- DMPA SC can be used by individuals of all ages, including adolescents.
- Body weight: No dosage adjustment of DMPA SC is necessary based on body weight.

Typical Use

Approximately 4 out of 100 individuals will become pregnant in the first year of use of DMPA SC with typical use, which is the same as provider-administered DMPA-IM.⁸

Medical Eligibility

To determine if the patient is a candidate for the Depot Medroxyprogesterone Acetate, the U.S. Medical Eligibility Criteria can be utilized based on the patient's medical history.³

¹ Pfizer. Patient Information DEPO-SUBQ Provera 104. (December 2019).

² Office of the Commissioner. "Understanding Unapproved Use of Approved Drugs 'Off Label'" U.S. Food and Drug Administration (2018).

³ American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice, "Over-the-Counter Access to Hormonal Contraception," *Obstetrics & Gynecology* 134, no. 4 (2019).

⁴ Cameron, Sharon T., Anna Glasier, and Anne Johnstone. "Pilot study of home self-administration of subcutaneous depo-medroxyprogesterone acetate for contraception." *Contraception* 85.5 (2012): 458-464.

⁵ Williams, Rebekah L., Devon J. Hensel, and J. Dennis Fortenberry. "Self-administration of subcutaneous depot medroxyprogesterone acetate by adolescent women." *Contraception* 88.3 (2013): 401-407.

⁶ Prabhakaran, Sujatha, and Ashley Sweet. "Self-administration of subcutaneous depot medroxyprogesterone acetate for contraception: feasibility and acceptability." *Contraception* 85.5 (2012): 453-457.

⁷ Beasley, Anitra, et al. "Randomized clinical trial of self versus clinical administration of subcutaneous depot medroxyprogesterone acetate." *Contraception* 89.5 (2014): 352-356.

⁸ National Family Planning & Reproductive Health Association (NFPFHA). *Reproductive Resource Guide: Self-Administration of Injectable Contraception*. (Updated April 13, 2020).n 89.5 (2014): 352-356.

Use of DMPA SC

The following information addresses protocols for initiation of DMPA SC 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 applicable, include information about whether Registered Nurses (RNs) or pharmacists can furnish DMPA SC 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 SC. In particular, the patient's willingness to learn the self-administration technique, prior experience of pain with office injections, and 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 the initiation of DMPA SC. A baseline weight measurement (may be performed at home by the patient and disclosed to the clinician) will help with monitoring patients over time for those patients concerned about weight gain. Screening for hypertension before initiation of DMPA SC is not necessary.

Counseling Points

NOTE: If your health center or system has a clinical protocol related to contraceptive counseling, list title and location [here](#).

Amenorrhea and unscheduled spotting or light bleeding are common side effects with DMPA SC use, while heavy or prolonged bleeding is uncommon. These bleeding irregularities generally are not harmful and might decrease with continued use. Inform patients that they can always contact the health center if they experience any side effects, and they will be scheduled for an in-person or telehealth appointment, based on the patient's desire. DMPA still contains a black-box warning for decreased bone density. This decrease in bone density is reversible upon discontinuation of DMPA and has not been shown to correlate with clinical outcomes of fracture.

Initiation of DMPA SC

Timing

- The first DMPA SC injection can be given at any time if it is reasonably certain that the patient is not pregnant.

NOTE: If the health center or system has an algorithm for initiating hormonal contraception included in another clinical protocol, list title and location [here](#).

- Offer in-clinic pregnancy tests or at-home options if warranted

Need for backup 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 should abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.

In situations in which the health care provider cannot determine the patient's pregnancy status, the benefits of starting DMPA SC may outweigh risk (there have not been any evidence-based studies showing risk to a fetus or pregnant person who has used DMPA); therefore, starting DMPA SC should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. If the patient needs to use a backup method when switching to DMPA SC from another contraceptive method, consider continuing their previous method for 7 days after the DMPA SC injection.

Reinjection Interval

- The package insert for Depo SC 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 that only included DMPA IM. However, studies among users in Africa suggest that the same 15-week limit also applies to DMPA SC.
- 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 should 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).
 - » Discuss with patients the best way for them to remind themselves about dates for reinjection. Alternatively, health centers can set up telephone, chart, or text messaging 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.
- Some individuals have found it beneficial to have a friend, family, or community member administer the injection.
- Simplified step-by-step instructions:
 1. Wash hands.
 2. Remove syringe from package and shake it for 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

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

- [Bedsider, Birth Control Reminder App](#)
- [Reproductive Health Access Project, Progestin Injection 15-week Cycle Calendar](#)

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