




# Self-Administration of Injectable Contraception

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# Self-Administration of Injectable Contraception

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## Self-Administration of Injectable Contraception

Depot medroxyprogesterone acetate (DMPA) is an injectable contraceptive method used by four percent of women using contraception in the US. DMPA, which is given once every 12-15 weeks, can be administered in two ways: intramuscularly (IM) 150 mg or subcutaneously (SQ) 104 mg. During the COVID-19 pandemic, family planning providers are considering offering the use of SQ formulation directly to patients for self-injection to reduce visits to health centers.

### Introduction

As a result of the COVID-19 public health emergency, family planning providers are reevaluating the way in which their patients can access contraception in general and DMPA specifically. Some health centers continue to offer DMPA injections as an in-person visit, while others have begun offering initial or repeat DMPA injections as a “curbside” service in which the patient remains in their car while the injection is administered by a clinician. Many family planning providers have expressed interest in providing DMPA SQ supply directly to patients for self-injection to reduce the need for in-person visits to health centers. The following information may be useful to organizations interested in exploring patient administered DMPA SQ for the first time.

## Self-Administration of Injectable Contraception

### Comparison of DMPA SQ and DMPA IM

The two routes of DMPA administration, SQ and IM, are equally effective and both have a typical-use failure rate of 4 pregnancies per 100 women per year. DMPA SQ has two major differences from DMPA IM: a reduction in dosage by about one-third, as well as a delivery system that uses a smaller needle and one-third less injected fluid volume. The prefilled DMPA SQ syringe uses a 26-gauge x 3/8-inch needle, which is comparable to other drugs that are self-injected. These characteristics, plus the fact that the injection is placed into the skin, and not deep into a muscle, may make the injection less painful than DMPA IM for some women. Observational studies from a global setting show patient preference<sup>1,2</sup> for the SQ formulation over the IM due to fewer side effects and less pain.

DMPA IM is available in both brand name (Depo-Provera) and generic versions; DMPA SQ is available only as a brand-name product (depo-subQ provera 104).

Method of Injection	Needle Type	Dosage	Packaging	Manufacturer
Subcutaneous (SQ)	26-gauge x 3/8-inch needle	104 mg / 0.65 mL	Single-dose prefilled syringe	Pfizer
Intramuscular (IM)	22-gauge x 1 1/2-inch needle	150 mg / 1 mL	Vial or single-dose prefilled syringe	Pfizer Teva Generics Greenstone

### FDA Approval of DMPA SQ

DMPA SQ was approved by the US Food & Drug Administration (FDA) in 2004. It was developed originally to be self-injected; however, given that current FDA labeling states "Depo-subQ provera 104 is only for subcutaneous administration and is only to be administered by a healthcare professional"<sup>3</sup>, prescribing it to a patient for self-injection is considered an "off-label"<sup>4</sup> use. While DMPA SQ is not labeled by the FDA for self-injection, **several studies have demonstrated the safety and feasibility of self-administered DMPA SQ.**<sup>5</sup>

Since prescribing it to a patient for self-injection is an off-label use, 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 medical record.

<sup>1</sup> Burke HM, Mueller MP, Perry B, et al. Observational study of the acceptability of Sayana® Press among intramuscular DMPA users in Uganda and Senegal. *Contraception*. 2014; 89(5):361-367.

<sup>2</sup> Cover J, Ba M, Drake JK, et al. Continuation of self-injected versus provider-administered contraception in Senegal: a nonrandomized, prospective cohort study. *Contraception* 2019; 99:137-41.

<sup>3</sup> Pfizer, depo-subQ provera 104 Prescribing Information. Accessed: <http://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=549>.

<sup>4</sup> US FDA, Understanding Unapproved Use of Approved Drugs "Off Label". Accessed: [www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label](http://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label).

<sup>5</sup> Kennedy CE, Yeh PT, Gaffield ML, Brady M, Narasimhan M. Self-administration of injectable contraception: a systematic review and meta-analysis. *BMJ global health*. 2019; 4(2):e001350.

## Self-Administration of Injectable Contraception

### Clinical Considerations

#### Safety and Efficacy of Self-Administered DMPA SQ

A systematic review and meta-analysis<sup>6</sup> published in 2019 concluded that self-administration of DMPA SQ can equal or improve contraceptive continuation rates compared with provider administration. This approach increases contraceptive use without notable increases in pregnancy or safety concerns. Additionally, there are number of studies of DMPA IM compared to DMPA SQ in the US. A systematic review<sup>7</sup> published in 2016 concluded that among healthy women, DMPA SQ and DMPA IM appear to be therapeutically equivalent. For example, the systematic review includes data from a large randomized controlled trial<sup>8</sup> in which 401 patients ages 16–44 seen at Planned Parenthood centers in New Jersey and Texas requesting DMPA were randomly assigned to either self-administration of DMPA SQ or clinic-administration of DMPA IM. The results included the following findings:

- At one year, 69% of people in the self-administration group had used the shot continuously (i.e., no gaps in use), compared to 54% in the clinic group, a 15% difference.
- Satisfaction with DMPA at 12 months was high and similar between the self-administration and clinic groups.
- Among the self-administration group, 97% reported that self-administration was very or somewhat easy, and 87% said they would recommend it to a friend.
- Among the clinic group, 52% said that they would be interested in self-administration in the future.

#### Candidates for DMPA SQ

- Patients who are have chosen to initiate this method.
- Patients who currently receive DMPA IM, and who after counseling, opt to switch to this delivery route.
- DMPA SQ can be used by anyone and may be a particularly good choice for patients who are experienced in self-injection of other drugs (such as medications to induce ovulation for in-vitro fertilization, insulin, low molecular weight heparin, or drugs for multiple sclerosis).

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 medical record.

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<sup>6</sup> Kennedy CE, Yeh PT, Gaffield ML, Brady M, Narasimhan M. Self-administration of injectable contraception: a systematic review and meta-analysis. *BMJ global health*. 2019;4(2):e001350

<sup>7</sup> Dragoman MV, Gaffield ME. The safety of subcutaneously administered depot medroxyprogesterone acetate (104mg/0.65mL): A systematic review. *Contraception*. 2016 Sep;94(3):202-15

<sup>8</sup> Kohn JE, Simons HR, Della Badia L, Draper E, Morfesis J, Talmont E, Beasley A, McDonald M, Westhoff CL. Increased 1-year continuation of DMPA among women randomized to self-administration: results from a randomized controlled trial at Planned Parenthood. *Contraception*. 2018 Mar;97(3):198-204.

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### Contraindications

The contraindications and precautions for DMPA SQ are the same as DMPA IM. The Centers for Disease Control and Prevention (CDC) [Medical Eligibility Criteria, 2016](#) (US MEC) lists DMPA categorization as:

- **Category 4**<sup>9</sup>: Breast cancer treated within the past five years
- **Category 3**<sup>10</sup>:
  - Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)
  - Systolic  $\geq 160$  mm Hg or diastolic  $\geq 100$  mm Hg
  - Hypertension with vascular disease
  - Current and history of ischemic heart disease
  - History of stroke
  - Systemic lupus erythematosus (initiate:
    - Positive (or unknown) antiphospholipid antibodies (initiation and continuation of the method)
    - Severe thrombocytopenia (initiation of the method only; continuation of DMPA is Category 2<sup>11</sup>)
  - 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 more than 20 years' duration
  - Cirrhosis; severe, decompensated
  - History of benign or malignant liver tumor

### Use of DMPA SQ

The use of DMPA SQ is largely the same as DMPA IM. The [CDC US Selected Practice Recommendations for Contraceptive Use, 2016](#) (US SPR) includes the following recommendations:

- **Timing**
  - The first DMPA injection can be given at any time if it is reasonably certain that the woman is not pregnant.
- **Need for back-up contraception**
  - If DMPA is started within the first seven days since menstrual bleeding started, no additional contraceptive protection is needed.
  - If DMPA is started more than seven days since menstrual bleeding started, the woman needs to abstain from sexual intercourse or use additional contraceptive protection for the next seven days.

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<sup>9</sup> Category 4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

<sup>10</sup> Category 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.

<sup>11</sup> Category 2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

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- **Switching from another method**
  - *From 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).
  - *From an implant:* administer the first injection of DMPA SQ on the day of implant removal.
  - *From a 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
  - *From an IUD:* If the patient chooses to have the IUD removed on the day of initiation of DMPA and had sexual intercourse more than five days since menstrual bleeding started, residual sperm might theoretically be in the genital tract, which could lead to fertilization if ovulation occurs. Consider any of the following options:
    - Advise the patient to retain the IUD for at least seven days after the injection and return for IUD removal.
    - Advise the patient to abstain from sexual intercourse or use barrier contraception for seven 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 seven days, advise the patient to use emergency contraception (EC) (except for ulipristal acetate (UPA)) at the time of IUD removal.
- **Screening tests before initiation**
  - While the SPR states that a baseline weight and body mass index (BMI) measurement might be useful to monitor DMPA users over time, self-reporting of weight and height are acceptable.
  - Screening for hypertension before initiation of DMPA is not necessary.
- **Reinjection interval**
  - The package insert for depo-subQ provera 104 expressly states that the recommended injection interval is every 12-14 weeks. This is different from the DMPA reinjection interval recommended in the SPR, which 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<sup>12</sup> published in 2009 which included only DMPA IM and there are no studies that have evaluated the efficacy of DMPA SQ beyond 14 weeks.
  - Late injections (adapted from US SPR):
    - If more than two weeks late for a repeat DMPA injection (more than fourteen weeks for DMPA SQ or more than fifteen weeks for DMPA IM), 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

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<sup>12</sup> Paulen ME, Curtis KM. When can a woman have repeat progestogen-only injectables--depot medroxyprogesterone acetate or norethisterone enantate? *Contraception*. 2009 Oct;80(4):391-408.

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protection for the next seven days. The patient might consider the use of levonorgestrel 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 their self-injections if patients so desire.
- **Management of unscheduled spotting or light vaginal bleeding, heavy bleeding, or amenorrhea**
  - Refer to US SPR, page 22.

### Patient Education

Ideally, patients starting this method should receive instruction in the self-injection 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-injection, as well as guidance on the proper disposal of needles.

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

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

Resource	Website
Bedsider, <i>Birth Control Reminder App</i>	<a href="http://www.bedsider.org/reminders">www.bedsider.org/reminders</a>
Reproductive Health Access Project, <i>Progestin Injection 15-week Cycle Calendar</i>	<a href="http://www.reproductiveaccess.org/wp-content/uploads/2016/04/Progestin-Injection-Perpetual-calendar-15-week-cycle.pdf">www.reproductiveaccess.org/wp-content/uploads/2016/04/Progestin-Injection-Perpetual-calendar-15-week-cycle.pdf</a>



## Self-Administration of Injectable Contraception

### 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 container
10. Apply light pressure to prevent bleeding without massaging.

### Ordering

DMPA SQ is currently available through multiple distributors. However, the 340B price of DMPA SQ has been very low in recent years, which has created a high demand for supply. As a result, some distributors may have restrictions on which organizations are eligible to have orders for DMPA SQ fulfilled.<sup>13</sup> Providers should contact their distributors to determine whether there is stock of DMPA SQ available. It has been reported that distributors may give preference to customers who have previously purchased the product.

In addition to the drug itself, providers may also want to consider providing patients with alcohol wipes and a sharps container.

### Storage and Patient Handling

Since DMPA should be stored at a controlled room temperature of 68° F to 77°F, it is important to instruct the patient not to refrigerate it or leave it somewhere that may reach a temperature outside of this range, such as a vehicle.

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<sup>13</sup> Health Resources and Services Administration, "Clarification on Penny Pricing Policy," 11/21/2011. Accessed: <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/pennypricingclarification112111.pdf>.

## Self-Administration of Injectable Contraception

### Coding and Billing

Product Name	depo-subQ provera 104
NDC #	0009-4709-13
HCPCS	J1050 (Injection, medroxyprogesterone acetate, 1 mg)
Unit Amount	J1050 x 103 units <i>The unit is calculated by mg. The first unit is included in the HCPCS code and remaining mg units are added separately.</i>

Payers may use modifiers or local codes for the DMPA product instead of J1050. Providers are encouraged to confirm the appropriate code use for individual payers.

### Patient Financial Assistance

DMPA SQ users may qualify for low-cost or no-cost services subsidized by state or federal programs or privately funded contraceptive access initiatives. However, if a patient does not qualify for financial assistance through one of these programs and needs financial assistance, there is a patient assistance program available to residents of the US and US territories through Pfizer, the manufacturer of depo-subQ provera 104. Enrollment in the Pfizer patient assistance program can be completed by the patient or the provider.

Pfizer Patient Assistance Program	
Online Enrollment	<a href="http://www.pfizerxpathways.com/start-enrollment">www.pfizerxpathways.com/start-enrollment</a>
Phone Enrollment <i>New Enrollees</i>	1-844-989-7284
Phone Enrollment <i>Existing Enrollees and Alaska or Hawaii Residents</i>	1-866-706-2400

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