**SYSTEMIC PROGESTIN-ONLY CONTRACEPTIVE METHODS: IDENTIFICATION OF CANDIDATE FOR INITIAL START OR RESTART**

| DEFINITION | Progestin-only methods are available as pills, injections, implants and IUDs. The two LNG-IUSs are described in *Identification of Intrauterine Device (IUD) Candidate* protocol. Many women prefer the convenience and efficacy of implantable and injectable progestin-only methods. A woman who experiences unacceptable estrogen-related side effects or who has contraindications to estrogen-containing contraceptive methods may be able to use progestin-only birth control methods successfully. Progestin-only methods may be preferred to combination hormonal methods for women with chloasma, hypertension, VTE, severe headaches, chronic asymptomatic hepatic disease, breastfeeding, tobacco use and age ≥ 35 with a BMI greater than 30. The typical use first year failure rate for progestin-only pills is the same as for conventional pills (9%) but failure rates may be lower in breastfeeding women. **Progestin-only implants** have first year failure rates that are at least as low as sterilization and with correct and consistent use may be as low as 0.1% and are not affected by obesity. Progestin-only implants are often more popular among adolescent women. The first year failure rate in typical use with the progestin-only injection (depo medroxyprogesterone acetate [DMPA] or Depo Provera®) is 6.4%, but with correct and consistent use, the failure rate is only 0.3%. DMPA is available in 2 formulations: DMPA 150 mg IM and depo-subQprovera 104®. DMPA offers many noncontraceptive health benefits, including reducing frequency of acute sickle cell crises, reducing the intensity of dysmenorrhea, treating severe anemia in women with excessive menstrual blood loss, and reducing the pain of endometriosis. It is likely that all progestin-only methods reduce the risk of endometrial cancer, especially in anovulatory women. Several studies have reported that structured counseling, especially about longer acting methods may be very useful in helping women choose more effective methods and maximize continuation rates. |

| SUBJECTIVE | Must include:  
| 1. LMP and PMP.  
| 2. Medical, sexual and contraceptive history (initial or update).  
| 3. Evaluation for allergies to any component of the method or to antiseptic or local anesthesia, if considering implant.  
| 4. History of any recent unprotected intercourse.  
| Must exclude:  
| 1. Any US MEC category 4 conditions for desired method.  
| 2. Any US MEC category 3 conditions for desired method prior to MD approval.  
| NOTE: Breastfeeding women can initiate any systemic progestin-only method immediately postpartum, despite labeling recommendations, as long as the women can tolerate a slight increase in lochial blood loss. There is no increase in postpartum depression due to progestin-only methods. |

| OBJECTIVE | May include:  
| 1. BP. Obtain MD consult if BPS ≥ 160 or BPD ≥ 100 mm Hg. (for implant and injection).  
| 2. Weight, BMI (obesity is not a contraindication to any progestin-only method. The efficacy of implants and injections is not affected by patient weight.)  
| NOTE: Progestin-only methods may be initiated or restarted without pelvic examination in asymptomatic women who have not had recent exams. Routine STI testing may be performed using urine specimens, if indicated. |

| LABORATORY | Must include: Negative sensitive urine pregnancy test (UCG) only if patient has unexplained irregular or delayed menses or symptoms of pregnancy. Routine pregnancy testing is unwarranted. There may be more need to document that pregnancy has been ruled out for implant candidates seeking placement at unconventional times. |
### ASSESSMENT
Candidate for systemic progestin-only hormonal method.

### PLAN

1. Obtain MD consult if any US MEC category 3 conditions for desired method.
2. If **progestin-only birth control pills** are selected, patient may start in one of 2 ways:
   - a. Immediately with Quick Start (preferred approach):
     1) If LMP \( \leq 5 \) days earlier, start today with no back up method needed.
     2) If LMP > 5 days earlier, management depends upon history of recent unprotected intercourse (see Attachment 1).
       - a) If no unprotected intercourse since LMP:
         1) Have patient start progestin-only pill immediately. Advise her to use abstinence or use back-up method for 7 days.
         2) Provide 12 month supply of pills, if possible. Return appointments may be scheduled earlier, as needed.
         3) Provide hormonal EC in advance of need if possible. See *Emergency Contraception (EC)* protocol.
       - b) If unprotected intercourse in last 5 days:
         1) Provide EC today according to *Emergency Contraception [EC]* protocol. The patient can start her pills the following day.
           - a) Have patient use abstinence or back-up method for 7 days after starting progestin-only pills. Her next menses may be delayed.
         2) Have patient get UCG in 3 weeks if she does not have a normal menses by then.
         3) Provide 12 month supply of pills, if possible. Return appointments may be scheduled earlier, as needed.
         4) Provide EC in advance of need. See *Emergency Contraception [EC]* protocol.
     3) If any unprotected intercourse >5 days earlier, use one of the following options:
       - a) Consider pregnancy test, as indicated. Advise patient that pregnancy test may not be 100% accurate.
         1) If pregnancy test is negative, have patient start progestin-only pills today and use abstinence or back-up method for 7 days.
         2) If no pregnancy test is indicated, have patient start progestin-only pills today and use abstinence or back-up method for 7 days.
         3) Have patient get UCG in 3 weeks if she does not have a normal menses.
         4) Provide 12 month supply of pills, if possible. Return appointments may be scheduled earlier, as needed.
         5) Provide EC in advance of need. See *Emergency Contraception [EC]* protocol.
       - b) First day of next menses (less preferred approach).
         1) Provide interval method.
         2) Have patient start her first pill on the first day of her next menses. No back-up method needed.
         3) Provide 12 month supply of pills, if possible. Return appointments may be scheduled earlier, as needed.
         4) Provide EC in advance of need. See *Emergency Contraception (EC)* protocol.
3. If **DMPA** is selected, administration depends on date of LMP and current method used.
   - a. If LMP \( \leq 7 \) days ago or if switching from an effective method such as IUD, implant, combined hormonal method, last DMPA injection given < 15 weeks and no symptoms of pregnancy, give DMPA with either one of the following:
     1) DMPA 150 mg deep IM injection in deltoid area of the arm or upper outer quadrant of buttoc using a 21-23 gauge needle. Do not massage area after injection. No back-up method needed.
     Note: In obese women, deltoid injection preferred. Spinal needles may be needed to reach muscle in gluteus of woman with BMI over 30.
2. OR

   2) depo-subQprovera 104 subcutaneously over 5–7 seconds in anterior thigh or abdomen (except near umbilicus). No back-up method needed.

   b. If LMP > 7 days ago and if not switching from effective methods as noted above, two options are available:

      1) Quick Start (same day) injection (preferred approach).

         a) If no unprotected intercourse since LMP (or since last contraceptive effective), provide DMPA as outlined above and advise the use of abstinence or back up method for 7 days.

         b) If any unprotected intercourse since LMP or date since last contraceptive effective, determine need for UCG. If not indicated or if UCG negative:

            (1) If unprotected intercourse in prior 5 days, offer EC (See Emergency Contraception [EC] protocol).

               a) If patient accepts EC, patient may also be given DMPA at this visit. Instruct her to use abstinence or back-up method for 7 days. If she has had any unprotected intercourse since LMP, recommend repeat UCG in 2-3 weeks if no menses, or if she has any signs or symptoms of pregnancy.

               b) If patient declines EC, recommend abstinence or provide barrier method for 14 days. Have patient return in 14 days for repeat urine pregnancy test. If that test is negative, administer with DMPA and have patient use abstinence or back-up method for 7 days. If menses returns before 14 days, patient may return for injection on menses and avoid need for back-up method.

            (2) If last intercourse > 5 days ago, offer urine pregnancy test. If UCG negative, advise patient that test may be too early to detect pregnancy, but that DMPA has no known adverse effects on fetus.

               a) Offer DMPA and recommend abstinence or back-up method for 7 days. Suggest repeat UCG in 2-3 weeks if no menses, or if any signs or symptoms of pregnancy.

               b) If UCG negative, but patient desires to wait for injection, recommend abstinence or provide barrier method for 14 days. Have patient return in 14 days for repeat urine pregnancy test. If that test is negative, inject with DMPA and have patient use abstinence or back-up method for 7 days. If menses returns before 14 days, patient may return for injection on menses and avoid need for back-up method and UCG.

   c. DMPA may be given immediately after pregnancy loss or termination, and to postpartum women before they are discharged home after delivery whether or not they are breastfeeding unless the woman has severe anemia or heavy bleeding. There is no increase in the risk of postpartum depression with immediate postpartum use of DMPA. DMPA has not been shown to reduce breast milk production or duration of breastfeeding.

   d. Calculate date of next injection and schedule next visit.

      (1) DMPA 150 mg IM: 11-13 weeks.

      (2) depo-subQprovera 104®: 12-14 weeks.

   e. For women who have had previous problems or concerns with unscheduled bleeding with DMPA and no category 3 or 4 conditions for COCs, consider pre-treating with COCs for 2 months prior to first DMPA injection.

   f. Offer EC in advance of need (See Emergency Contraception [EC] protocol)

4. If implant selected, place only if confident patient is not pregnant:

   a. No backup method is needed if implant placed at any of the following times:

      1) During first 5 days of menses.

      2) At any time if switching from combined hormonal contraception, including hormone free intervals of COCs, patch or vaginal ring.

      3) At any time if switching immediately from progestin-only method, including progestin-only pills, DMPA injection, LNG-IUD or implant.

      4) If exclusively breastfeeding, and amenorrheic in the first 6 months following delivery,
**PLAN (Continued)**

- May place immediately if no recent unprotected intercourse.
- Within 5 days of first trimester pregnancy loss.
- Within 28 days after second or third trimester pregnancy loss or delivery.

**b.** If placing at any other time, confirm pregnancy test negative, provide EC, if needed, and advise abstinence or provide barrier method for 7 days after implant placement.

**c.** If placing this visit:

1. Explain risks and benefits of implants. Counsel about bleeding changes that may be expected.
2. Obtain informed consent using manufacturer’s informed consent form or a local form that includes all the information found in FDA-approved form.
3. Place implant according to manufacturer’s instructions.
4. Verify placement of implant.
5. Provide post-placement instructions and precautions. Advise abstinence or back-up contraception for 7 days, if needed.

**d.** Have patient return for annual examination and PRN problems.

**PATIENT EDUCATION**

1. Remind the patient that any of these methods of contraception is safer for her health than pregnancy would be.
2. Advise women that progestin-only methods do not protect against STIs, including HIV. Recommend safer sex practices if patient is at risk for STIs.
3. **Progestin-only pills:**
   a. Review progestin-only pill instructions:
      1. Reinforce need for short term use of barrier method if using Quick Start (see Attachment 1).
      2. Advise patient to take one pill at the same time each day. Do not stop use during menses.
      3. Tell patient that progestin-only pills do not regulate menstrual cycle; she will bleed according to her own body’s cycle. Infrequent menses does not pose a risk for endometrial cancer for women using progestin-only pills. In the absence of other signs or symptoms of pregnancy, no testing is needed.
   4. Missed pill instructions:
      a. If ≤ 3 hours late in taking her pill, advise her to take missed pill as soon as possible and use abstinence or other back-up method for 2 days.
      b. If > 3 hours late in taking her pill and she has had otherwise unprotected intercourse in last 3 days, advise her to use EC. (See Emergency Contraception [EC] protocol). Have patient restart pill tomorrow and use abstinence or a back-up method for 7-14 days. Suggest UCG if no menses in 3 weeks or if symptoms of pregnancy develop.
      c. If > 3 hours late in taking her pill but has not had any intercourse in last 5 days, have patient take today’s pill now, continue with daily pills and use abstinence or back up for 7 days. Suggest UCG if next menses delayed by more than 1 week or if symptoms of pregnancy develop.
   b. Instruct patient about possible menstrual changes with progestin-only pills:
      1. Most women will experience menstrual changes. Most women experience a reduction in total blood loss, but the timing of the bleeding depends upon the woman’s own body cycle. It is not possible to predict which of the following patterns any individual woman may have:
         a. Regular, predictable cycles.
         b. Irregular bleeding cycles.
         c. Spotting, unscheduled bleeding.
         d. Prolonged but generally lighter cycles.
         e. Amenorrhea (least frequent pattern).
      2. Advise patient to take progestin-only pill during menses and even when she has spotting or bleeding between regular bleeding episodes.
   3. Use menstrual calendar if patient has menstrual irregularities.
   4. Recommend she RTC for pregnancy test if symptoms of pregnancy occur.
| PATIENT EDUCATION (Continued) | c. Warn patients about rare serious side effects. These side effects are not generally due to the pill, but they do warrant immediate evaluation. Advise patient that if she has heavy bleeding or if she has unusually strong cramping, abdominal pain or fever, she should return for exam or go to ER. These symptoms may represent ectopic pregnancy, an ovarian cyst or a miscarriage.  

|  | d. Advise breastfeeding patient to return when planning to discontinue breastfeeding or planning to add supplemental feedings to infant, if she desires to use a combined hormonal method.  

|  | **4. DMPA:**  
|  | a. Advise patient that if she needed EC and does not menstruate in the 3 weeks following her injection, she should get repeat pregnancy test.  
|  | b. Advise patient to return for repeat injection in 11-13 weeks if DMPA 150mg IM given or in 12-14 weeks if depo-subQprovera 104® given. Stress the importance of timely reinjections to enjoy the full contraceptive potential of this method.  
|  | c. Advise patient about possible menstrual changes with DMPA including irregular menstrual bleeding, spotting or unscheduled bleeding, prolonged bleeding, diminished and/or no bleeding. Over time, most women stop all bleeding and spotting. Counsel women that the absence of bleeding in DMPA is a significant health benefit and does not indicate that they are menopausal or have long term infertility. Amenorrhea can be especially beneficial for active women, those with physical disabilities and those who suffer pain or heavy blood loss with menses.  
|  | d. Advise patient of possible weight changes and other potential side effects including headache, mood swings, hair changes, and other problems listed on package insert. Remind her that these problems are often not due to DMPA, but she should return to be evaluated if they bother her. In particular, studies show that some weight gain attributable to DMPA may be seen in teens, but not in adult women. Rarely women have an anaphylactic reaction immediately following injection.  
|  | e. Instruct patient to change her method 6-18 months prior to attempting pregnancy. Advise patient that fertility (ovulation) may not return for up to 2 years, but that half the women will ovulate within 10 months of their last injection.  
|  | f. Remind patient that all women need adequate calcium intake. Recommend calcium supplementation if patient’s daily diet provides less than adequate amounts (1000 mg adult women; 1300 mg adolescent women).  
|  | g. Counsel patients about the injection administration. Answer concerns related to needle apprehension.  
|  | h. Advise patient using DMPA that temporary but reversible bone loss can occur. Some subgroups may experience higher fractures.  
|  | i. Advise patient to RTC if she experiences heavy vaginal bleeding, symptoms of pregnancy or other serious problems.  

|  | **5. Implant:**  
|  | a. Inform patient that she should:  
|  | 1) Keep the pressure dressing on for 24 hours.  
|  | 2) The Steri-strips can be taken off in 3-5 days, although it is better to wait until they fall off by themselves. Steri-strips should not be removed by patient until scab over the placement site has fallen off.  
|  | 3) If her arm is sore, she may also take Tylenol or Ibuprofen for the discomfort or place ice packs (20 minutes an hour) as needed. |
b. Advise patient to expect slight bruising and soreness around implant site for a few days after placement, and that the implant may be slightly visible after healing.

c. Advise patient to watch for these rare warning signs and seek medical care promptly if any of the following appears:
   1) Bleeding from the placement site.
   2) Increasing tenderness, redness, warmth or pus around the implant.
   3) Fever, chills.
   4) Any sign that the implant is being expelled.

d. Advise patient that protection from pregnancy begins immediately if placement is timed according to manufacturer’s recommendation. Otherwise she should not rely on the implant alone for 7 days after placement.

e. Advise patient that bleeding may be less predictable with implant use. Over time, she will usually have less bleeding.
   1) Counsel her that if her bleeding is acceptable in the first 3 months, she can expect that following cycles will be acceptable.
   2) If her first 3 cycles are abnormal, tell her that she has a 50% chance that her bleeding will improve in subsequent months. The time between periods may vary and she may have spotting in between periods.
   3) Suggest she keep a menstrual calendar and carry a light day panty liner with her.

f. Remind her to use back up methods if she starts using any St. John’s Wort or prescription drugs that can reduce the effectiveness of her implant.

g. Counsel patient that there is no harm to her health if she misses her periods, but instruct her to return for pregnancy testing if she has any symptoms of pregnancy or is concerned about the possibility of pregnancy.

h. Advise patient of possible weight changes and other potential side effects including headache, mood swings, hair changes, prolonged ovarian cysts and other effects listed on package insert.
   1) Remind her that most of those “side effects” are not due to the implant. For example, in a trial comparing the implant with a non-hormonal IUD, both groups of women gained the same amount of weight.

i. Advise her to always mention her implant whenever she is seen by medical personnel/clinician.

j. Remind her that the implant is effective for 3 years. Tell her she will be given a user card that will remind her of this date. Remind her that she is to keep the card in a secure place. Advise patient that a new implant may be placed in 3 years if desired.

k. Counsel her that fertility returns promptly after removal of her implant.

l. Advise patient that she may request to have her implant removed at any time for any reason.

m. Encourage patient to return for routine well woman exams.

REFER to MD/ER

1. Patient with US MEC category 3 conditions for the method she desires.
2. Patient with US MEC category 4 conditions for the method she strongly desires.
3. Patient who declines pelvic examination but has symptoms or signs indicating need for evaluation.
4. Patient with a difficult implant removal.
5. Patient with anaphylactic shock with DMPA or other procedures.

REFERENCES

5. Canto De Cetina TE, Canto P, Ordoñez Luna M. Effect of counseling to improve compliance in
<table>
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<th>REFERENCES (Continued)</th>
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### Summary of Recommendations for Method Initiation and for Management of Inconsistent Use of Systemic Progestin-Only Birth Control Methods (except LNG IUS)

<table>
<thead>
<tr>
<th>Initiating Method Use</th>
<th>Number of Days Back-up Method or abstinence Needed</th>
<th>EC Needed If Any Unprotected Coitus In Last 5 days*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Progestin-Only Pills</strong></td>
<td></td>
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<tr>
<td>Starting cycle day 1-5 of cycle</td>
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</tr>
<tr>
<td>Starting cycle day 6 or later</td>
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<tr>
<td><strong>DMPA</strong></td>
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<tr>
<td>Starting cycle day 1-7</td>
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<td>Starting cycle day 8 or later</td>
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<td><strong>Implant</strong></td>
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<tr>
<td>Starting cycle day 1-5</td>
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<tr>
<td>During hormone free interval of OCs, patch or vaginal ring</td>
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<td>At any time with progestin-only pills</td>
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<tr>
<td>At time next DMPA injection is due (up to 15 weeks from last injection)</td>
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<tr>
<td>At time of implant or IUD removal</td>
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<tr>
<td>Within 5 days of first trimester pregnancy loss</td>
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<td>Within 28 days after 2nd trimester pregnancy loss</td>
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<tr>
<td>Within 28 days after 3rd trimester delivery</td>
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<td>Exclusively breastfeeding in the first six months and amenorrheic with no unprotected intercourse</td>
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<td>Placement at any other time</td>
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<td><strong>Interruption of Use</strong></td>
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<td><strong>Progestin-Only Pills</strong></td>
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<tr>
<td>1 pill late by less than 3 hours</td>
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<td>1 or more pills late by more than 3 hours</td>
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<td><strong>DMPA</strong></td>
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<tr>
<td>Last injection up to 15 weeks ago if no pregnancy symptoms</td>
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</tr>
<tr>
<td>Last injection &gt;15 weeks ago</td>
<td>7</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* If unprotected intercourse in last 5 days, consider repeat pregnancy test in 3 weeks if no menses.