



Massachusetts Department of Public Health Emergency Contraception

Model Standing Order

Overview of Pharmacy Access Program

The procedures and protocols in this model standing order for emergency contraception reflect current medical knowledge and clinical best practice as of April 2015. The participating physician must sign and submit the standing order, which may be modified according to their clinical practice and experience.

1. A copy of the standing order must be maintained on file and readily retrievable at each participating pharmacy site, as well as filed with the Board of Registration in Pharmacy (Board) via email at pharmacy.dph-ec@state.ma.us. Proof of training must also be readily retrievable at each site. For more information on training, visit www.mass.gov/emergencycontraception.
2. By August 1st of each year, all pharmacies participating in the Massachusetts (MA) Pharmacy Access Program must report **the total number of emergency contraception (EC) units dispensed pursuant to a Standing Order for the period July 1–June 30** to the Massachusetts Department of Public Health (MDPH) by:
 - fax to 617-624-6062, attn: MDPH Family Planning Program, or
 - email (as an attachment) to pharmacy.dph-ec@state.ma.us

Emergency Contraception Overview

► Emergency Contraception (EC) Indication

EC is indicated for pregnancy prevention (regardless of when the patient presents during the menstrual cycle) following:

- unprotected intercourse
- known or suspected contraceptive failure (e.g., *slipped, broken or leaked condom; delayed Depo-Provera injection; missed one or more oral contraceptive pills; IUD partially or totally expelled; spermicide tablet not dissolving; withdrawal failure, etc.*)
- sexual assault or reproductive coercion, and
- in advance of need due to the possibility of future contraceptive failure.

► Timing of EC Administration and Efficacy

There are two types of EC pills that have been approved by the U.S. Food and Drug Administration (FDA) to prevent pregnancy after unprotected sex or sexual assault:

1. **Single entity progestin, levonorgestrel products (LNG):** Plan B One-Step® and generic equivalents such as Next Choice One Dose®, MyWay®, TakeAction™, and others containing levonorgestrel, a progestin hormone found in many commonly used combination birth control products. The primary mechanism of action of LNG products is the delay or inhibition of ovulation.
 - The FDA has approved LNG to be initiated up to 72 hours (3 days) after unprotected sex. However, research has shown LNG to be **effective when initiated up to 120 hours (5 days)** after sex.^{1,2}
 - LNG is most effective when taken within the first 12 hours after unprotected intercourse. Effectiveness decreases as the time between unprotected intercourse and administration of EC increases. Therefore, it is important for women to take LNG **as soon as possible after unprotected sex or sexual assault.**⁴
 - LNG reduces pregnancy risk by 87-90% if taken within 72 hours of unprotected sex. If taken between 72–120 hours, it reduces pregnancy risk by 72–87%.²
 - LNG **does not affect a woman's ability to become pregnant in the future.** If LNG is taken when the woman is pregnant, or if pregnancy occurs despite use, it will not cause an abortion or harm the developing fetus.⁴

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For additional information and resources on how to establish or renew a standing order with a practicing physician and/or participating pharmacy in your area, visit www.mass.gov/emergencycontraception or contact the **MDPH Family Planning Program** at **1-617-624-6060** or pharmacy.dph-ec@state.ma.us.

There are two types of EC pills that have been approved by the U.S. Food and Drug Administration (FDA) to prevent pregnancy after unprotected sex or sexual assault:

2. Ulipristal Acetate (UPA): ella® contains ulipristal acetate, a progesterone agonist/antagonist that postpones follicular rupture. The likely primary mechanism of action is therefore inhibition or delay of ovulation. Additionally, alterations to the endometrium that may affect implantation may also contribute to efficacy.

- ▶ The FDA has approved UPA to be initiated up to 120 hours (5 days) after unprotected sex.⁵
- ▶ UPA is the most effective oral medication available for preventing pregnancy after unprotected sex.⁶
 - UPA has been shown to result in pregnancy rates up to 65% lower than the pregnancy rate following the use of LNG when administered in the first 24 hours, and up to 42% lower up to 72 hours after unprotected sex.⁶
 - UPA can prevent more pregnancies than single entity progestin EC once ovulation is about to occur because it can better prevent follicular rupture once the leading follicle has reached a larger size than other EC pills.⁶
- ▶ Unlike LNG, **the efficacy of UPA does not decline throughout the five days following unprotected sex.** In part, this is because UPA is able to prevent follicular rupture at a slightly later stage of follicular development than LNG.⁶
- ▶ UPA may reduce the contraceptive action of regular hormonal contraceptive methods. Advise patients given UPA to use a reliable barrier method of contraception for any subsequent acts of intercourse that occur in that same menstrual cycle.⁵

Note: There is little safety data available about the effect of UPA on pregnancy and breastfeeding outcomes, so patients who are unsure of their pregnancy status should be advised to take a pregnancy test before choosing UPA.⁵ Unlike LNG, UPA should not be taken by patients who are breastfeeding or think that they might already be pregnant.

Potential Impact of BMI/Weight on EC Efficacy:

 While many studies have shown EC to be effective for women of varying weights, a 2011 study designed to examine which women may be at risk for unintended pregnancy despite using EC reported that EC pill regimens may be less effective for women of higher weight/body mass index (BMI). **More research is needed to determine the potential impact of weight/BMI on the efficacy of EC pills.**^{6,7}

- ▶ **The most effective EC regimen for women regardless of weight is emergency insertion of the Copper T intrauterine device (Copper T IUD).** The Copper T IUD is 99.9% effective at preventing pregnancy when inserted up to 5 days after unprotected sex, and provides a highly effective, immediate and cost-effective ongoing method of birth control for up to ten years post-insertion.
- ▶ While **women greater than 165 pounds** may increase their odds of pregnancy prevention by choosing UPA or a Copper T IUD for EC, they **should not be denied access to LNG products**, especially if more effective options are not available, clinically indicated or acceptable to the patient.
- ▶ A supportive referral for Copper T IUD insertion may be provided to a nearby MDPH Family Planning Program by contacting 617-624-6060 or visiting **www.mass.gov/emergencycontraception**. Contact 617-616-1636 for assistance scheduling timely IUD insertion following sexual assault.
- ▶ Remaining questions may be directed to the physician signing this order or the MDPH Family Planning Program at 617-624-6060.

▶ Side Effects:

EC side effects are generally mild, and may include nausea and vomiting. An antiemetic may be considered to prevent or treat nausea and/or vomiting prior to use. Other short-term side effects may include fatigue, headache, dizziness, lower abdominal pain, or a change in the timing or flow of the next menstrual cycle.^{4,5}

- ▶ **Several daily combined estrogen/progestin oral contraceptive pills (OCPs)** have also been determined by the FDA to be safe and effective for use as EC. While some women may benefit from learning how to use higher doses of daily OCPs for EC when other options are not available, this method is not only less effective, but also increases the likelihood of experiencing side effects (like nausea and vomiting).⁶ More information on using OCPs for EC is available at **www.not-2-late.com**.

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Emergency Contraception Order

1. Assess patient indications for EC described above.
2. Screen for contraindications to EC:^{4,5}
 - Known, established pregnancy reported by the patient

Note: Use of EC is **not** contraindicated in women whose pregnancy status is **unknown**. A pregnancy test is not required before EC can be administered, although it is recommended prior to choosing ulipristal acetate (refer to the product's package insert for details).

3. Dispense EC according to the recommended schedule:

| Emergency Contraception Dosage, United States FDA-Approved Products for EC | | | |
|---|--------------|--------------------|--------------------------|
| Brand | Manufacturer | Tablets per Dose | Dose |
| ella [®] | Afaxys | 1 tablet per dose | 30 mg ulipristal acetate |
| Plan B One-Step [®] | Teva | 1 tablet per dose | 1.5 mg levonorgestrel |
| MyWay [®] | Gavis | 1 tablet per dose | 1.5 mg levonorgestrel |
| Take Action [™] | Teva | 1 tablet per dose | 1.5 mg levonorgestrel |
| Next Choice One Dose [®] | Watson | 1 tablet per dose | 1.5 mg levonorgestrel |
| AfterPill [™] | Syzygy | 1 tablet per dose | 1.5 mg levonorgestrel |
| Levonorgestrel | Perrigo | 2 tablets per dose | 1.5 mg levonorgestrel |

4. Dispense an anti-nausea medication if requested or indicated by prior history of nausea with EC (or OCP) use:

| Anti-Nausea Medication Dosage, United States FDA-Approved Over-the-Counter Products for Presumptive Treatment of Nausea | | |
|--|-----------------------------------|---|
| Generic Name | Strength per Dosage Unit | Dose |
| Dimenhydrinate | 50 mg per oral or chewable tablet | 12 years of age and older: 1-2 tablets every 4 to 6 hours as needed; Maximum of 8 tablets within a 24-hour period |
| Meclizine | 25 mg per tablet | 12 years of age and older: 1-2 tablets daily |

5. Provide patient instructions based on selected EC product:^{4,5}
 - Take one/two tablet(s) by mouth within 120 hours of unprotected intercourse.
 - If vomiting occurs within 2-3 hours of administration, an antiemetic should be considered and the dose can be repeated.
 - If menses does not occur within four weeks of EC use, a pregnancy test is indicated.
 - If patient experiences severe lower abdominal pain 3-5 weeks after EC administration, she should be evaluated by a physician for ectopic pregnancy.
 - A regular hormonal contraceptive method can be initiated or resumed immediately after taking LNG, or combined OCPs, or at the start of the next menses after taking UPA.
 - Encourage the patient to contact her primary care provider, women's health provider, or family planning clinic for follow-up, which may include requesting or refilling a primary birth control method and accessing STI/HIV prevention and treatment.

To find low- or no-cost Family Planning Programs (including birth control, STI testing and EC) or Rape Crisis Centers funded by the Massachusetts Department of Public Health, call **1-617-624-6060** or visit **www.mass.gov/dph/familyplanning**.

6. Additional instructions for pharmacists:



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