CONNECTICUT MEDICAL ASSISTANCE PROGRAM
DEPARTMENT OF SOCIAL SERVICES
&
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QUARTERLY NEWSLETTER

Pharmacist Prescribed Contraception in Connecticut

In 1957, 66 years ago, the Food and Drug Administration (FDA) approved the first hormone-based therapy for regulation of menstrual periods. In 1960, approval was granted for use as the first hormonal based contraceptive, profoundly changing societal norms.[1] Prior to hormone based contraceptives, birth control methods included abstinence, use of prophylactics such as condoms or diaphragms, illegal abortion, and sterilization. The birth of hormonal contraceptives (HCs) transformed women's ability to govern their own fertility and gained notoriety as the first and only medication to be referred to as "the pill.1"

Enovid 10 was the first combination HC on the market and contained extremely high doses of estrogen and progestin: 150 µg of mestranol and 9.85 mg of norethynodrel, whereas products today range from 20-50 µg and 0.1-3 mg respectively.[2,3,4] Although not fully understood at the time, adverse events associated with HCs include breast tenderness, breakthrough bleeding, headache, nausea, bloating, weight gain, and mood changes.[2] Less common side effects include cancer (breast, cervical, liver), venous thromboembolic events (VTE), stroke, and myocardial infarction.[2] Occurrence of side effects increases as dosages increase and cardiovascular risks are increased in women who smoke.

Image 1

As utilization of the pill climbed and awareness of side effects evolved, so did a national movement for educating women. The book *Our Bodies, Ourselves* empowered women to lobby for rights about their bodies, health, and sexuality.[5] This book, along with the feminist movement at the time, spurred opposition against high dose HCs. Another book, *The Doctor's Case Against the Pill,* shed light on HC clinical trials held in Puerto Rico that did not obtain informed patient consent and may have overlooked serious side effects.[6] These two books helped initiate senate hearings in the 1970s that promoted lower doses and shared information with the general public regarding risks and side effects.[3,6]

From the 1970s through the 1990s women's rights and fertility options continued to expand. In 1973, the U.S. Supreme Court ruled in favor of Roe v. Wade, making abortion a constitutional right. During the 1980s, women benefited from even lower doses of hormones, multiphasic monthly pills, and an increase in the number of women practicing healthcare.[3] During the 1990s, HC dosage forms expanded to include intravaginal rings, long acting injectables, implants, and intrauterine devices (IUDs).[3] These decades contributed to safer dosing, less side effects, multiple formulations, and better understanding of contraindications, warnings, and adverse reactions associated with HCs.[3] In June of 2022, the U.S. Supreme Court overturned Roe v. Wade, prohibiting the constitutional right to an abortion and leaving the decision of legality up to individual states. Today approximately half of all U.S. pregnancies are unintended.[7] Unintended pregnancies increase the risk for adverse mother and infant health issues, and increase the costs associated with care.[8] In an effort to expand patient access to care and prevent unintended pregnancy, Public Act 23-52 was signed into law in Connecticut in June of 2023. It will allow Connecticut pharmacists to prescribe hormonal contraceptives (HCs) and emergency contraception (EC) to patients beginning January 1, 2024.[9] Connecticut joins 29 other states and the District of Columbia that have passed legislation allowing pharmacists to prescribe HCs in some capacity (Image 2).[10,11]

At the time this article was written, regulations were still being finalized by the Department of Consumer Protection (DCP). Pharmacists should not prescribe these medications until the regulations have been approved. Proposed regulations and guidance documents can be accessed by visiting the DCP website.[12]

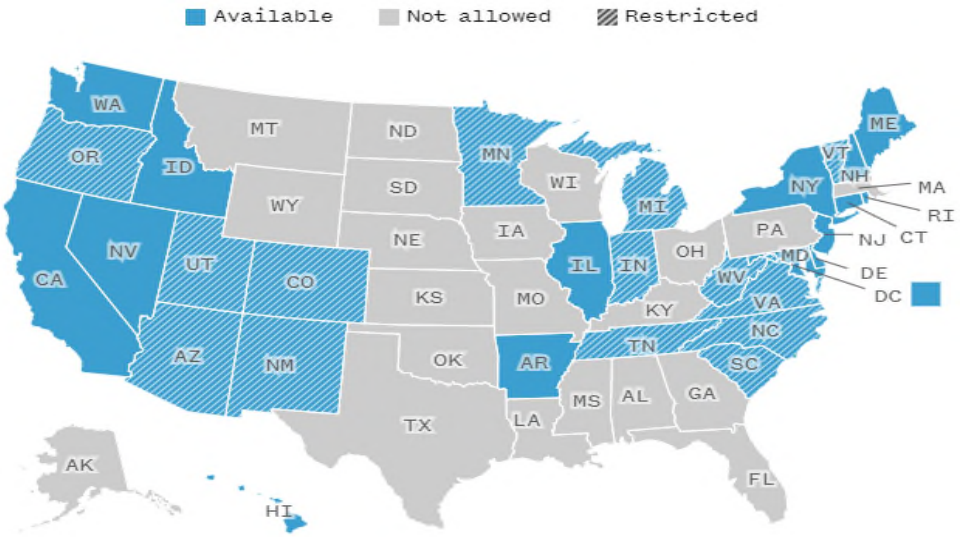
Connecticut pharmacists who plan to prescribe EC and HC must complete an accredited pharmacy education training program. The program will include information on interviewing and screening patients, documentation of medical history and any underlying disease states, identification of contraindications and drug interactions, selection of agents to prescribe, and appropriate times for referral to practitioners.[13] The World Health Organization (WHO) initially developed medical eligibility criteria (MEC) for contraceptive use with the intent that the publication would be used as a guideline by individual nations.[14] In response, the Center for Disease Control (CDC) published The United States Medical Eligibility Criteria (U.S. MEC) for Contraceptive Use to provide guidance and recommendations for the safe use of contraceptives in women.[8,15] In addition to completing a training program, Connecticut pharmacists who prescribe EC and HC must be familiar with the CDC's U.S. MEC recommendations.[8] Completion of the training program grants a certificate, valid for 24 months, authorizing the pharmacist to prescribe EC and HC.

Pharmacist Prescribed HC[12]

When a patient requests a prescription for a HC, the pharmacist must first determine the patient's age. Patients 18 years of age and older can receive a new prescription, however, patients younger than 18 years of age must have had a previous HC from a licensed practitioner for a pharmacist to prescribe another. If the

Pharmacist Prescribed Contraception in Connecticut

Image 2. States that have passed legislation to support pharmacist prescribed contraception



pharmacist plans to prescribe a continuation of a previously prescribed HC, the pharmacist must confirm the patient has been seen by the original prescribing practitioner within the last 3 years. Patients are required to complete the self screening tool and pharmacists are strongly encouraged to review the prescribing guide for general considerations. Pharmacy technicians who have completed a training program may assist with interviewing and screening patients. It is also required to obtain a patient's medical history and blood pressure reading. Pharmacists must then complete the HC treatment algorithm and the U.S. MEC for contraceptive use published by the CDC. These documents will assist the pharmacist in determining if HC is appropriate for the patient given their medical history, any underlying disease states, contraindications, or drug interactions. The DCP has posted draft versions of all HC specific documents here. If the evaluation of these documents indicates the pharmacist can prescribe, selection of an agent can be made. The screening tool, treatment algorithm, and U.S. MEC documents must be filed and kept for 3 years. If the evaluation indicates the patient has deviated from the questionnaires, the pharmacist may not prescribe HC and referral to the primary care provider is required.

Proposed regulations define pharmacist prescribed HC drugs to mean oral, patch, or intravaginal dosage forms. While other hormonal based contraceptives are available (implants and intrauterine devices (IUDs)), pharmacists are not authorized to prescribe these dosage forms. There are two distinct types of hormone-based contraception: combination estrogen and progestin products, and progestin only products.[8]

Estrogen and progestin work by suppressing gonadotropins, follicle stimulating hormone (FSH) and luteinizing hormone (LH), from the pituitary gland which ultimately inhibits ovulation (Image 3).[16] Progestin also works by thickening the cervical mucosa and thinning the uterine lining, which help to prevent pregnancy.[16] Combination hormonal contraceptives (CHCs) are available in many different products and dosage forms and include daily combined oral contraceptives (COCs), weekly patches, and monthly intravaginal rings.[8] Example products include Loestrin, Twirla®, and NuvaRing® respectively. While COCs are more effective at preventing pregnancy and have less breakthrough bleeding compared to POCs, they carry a higher risk of VTE.[16] Progestin only contraceptives (POCs) are available in oral, injectable, and implant dosage forms, however, pharmacists are only authorized to prescribe oral POCs. There are many oral prescription POCs on the market (Camila®, Micronor®, Errin®) and in July of 2023 the FDA approved the first OTC oral contraceptive, Opill.[17] Opill contains a lower dose of progestin compared to the prescription only products. POCs must be taken daily at the same time each day to ensure effectiveness, can be used during breastfeeding, and are preferred in women who are over the age of 35, women who smoke, have cardiovascular issues, or who cannot tolerate estrogen. POCs are associated with more breakthrough bleeding compared to COCs and should not be used in patients with a history of breast cancer.[16]

Product selection should be based on the individual patient, medical history, and personal preference. The pharmacist is required to provide the patient with verbal counseling, a written fact sheet, and a pharmacist referral and visit summary. The pharmacist referral and visit summary is required to include (at a minimum) the following:

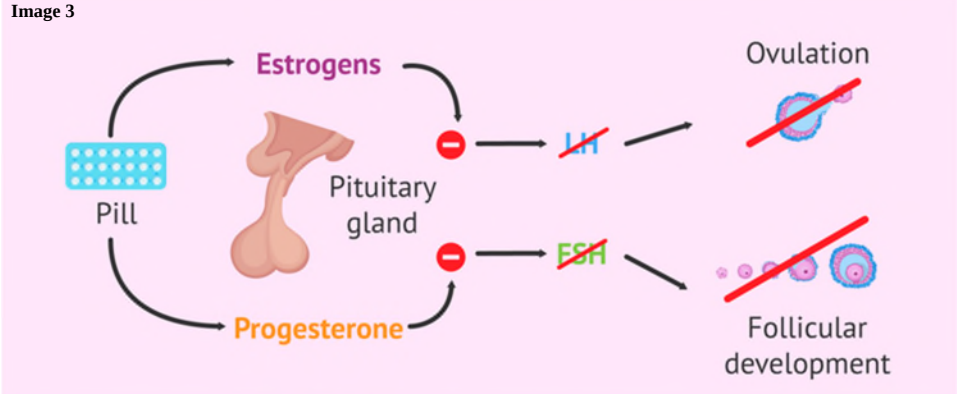
- Patient name and date of birth
- Name, practice address, and phone number for the prescribing pharmacist
- Date the prescription was issued
- Name and strength of the prescribed contraceptive
- Quantity and number of refills authorized (if any)

Prescriptions and refills for HCs are not to exceed 12 months. The screening tool, treatment algorithm, and U.S. MEC questionnaires are required to be completed every 12 months for new prescriptions. Additionally, communication must be sent to the patient's primary care regarding the HC prescription within 24 hours if the patient provides the provider contact information. If the contact information is not provided by the patient, the patient should be given all information and communication for their records.

Pharmacist Prescribed EC[12]

When a patient requests a prescription for an EC, pharmacists are required to administer the self-screening tool, the EC treatment algorithm, and the U.S. MEC for contraceptive use, classifications for emergency contraception. Phar-

Image 3



macy technicians who have completed a training program may assist with interviewing and screening patients. The DCP has posted draft versions of EC specific documents here. If the evaluation of these documents indicates the pharmacist can prescribe an EC, selection of an agent can be made. The screening tool and U.S. MEC documents must be filed and kept for 3 years. If the evaluation indicates the patient has deviated from the questionnaires, the pharmacist may not prescribe EC and referral to the primary care provider is required. There are currently 4 options for EC use in the U.S.: insertion of a copper intrauterine device (Cu-IUD), the Yuzpe method (prescribed COCs), over-the-counter (OTC) levonorgestrel (LNG), and prescription ulipristal acetate (UPA).[18,19] While Connecticut pharmacists are not authorized to prescribe implantable products or IUDs, it should be noted that insertion of a Cu-IUD is the most effective method of EC, however, it is not commonly used due lack of awareness and patient access.[18] Additionally, the Yuzpe method is not FDA approved and therefore pharmacists are not authorized to prescribe this course of treatment.

The two FDA approved oral options for pharmacist prescribed EC are LNG and UPA. LNG is a progestin only 1.5 mg oral tablet.[20] Initially approved in 1999 as a prescription, LNG has been available as an OTC product since 2013. LNG can be purchased without consulting a pharmacist; however, many insurance companies will reimburse the pharmacy if it is billed as a prescription. Use of LNG is preferred in patients who have had intercourse in the past 72 hours, weigh less than 155 pounds (lbs.), or who are requesting EC due to missed dose or late HC.[18] Prescription UPA is a progestin agonist/antagonist and inhibits ovulation by postponing follicular rupture.[21] UPA was approved in 2010 as a 30 mg oral tablet. Studies show that UPA is more effective compared to LNG when used 72 -120 hours post intercourse and in patients who weigh more than 155 lbs.[18] Despite its efficacy, patient and provider awareness of UPA is lacking and pharmacies do not typically stock this medication. Appreciation of UPAs benefits over LNG may be recognized as pharmacist prescribing training courses become more commonplace. As with HC, the prescribing pharmacist is required to provide the patient with verbal counseling and written educational material. A prescription for EC is a one-time fill with no refills. Communication must be sent to the patient's primary care and Obstetrician/Gynecologist (OBGYN) if contact information is provided. Counseling and provider recommendations should be provided to patients who do not have a primary care provider or OBGYN.

Pharmacists are often considered the front line of healthcare and pharmacist prescribed EC and HC contribute numerous benefits to families and society by providing greater access to care. EC and HC prevent unintended pregnancy, lower the rates of abortion, assist with cycle control and management of dysmenorrhea, contribute to lower rates of hysterectomy, and protect against uterine and ovarian cancer.[3] Long waits for scheduled appointments, restrictive office hours, and requirements for annual and pelvic exams are deterrents for patients seeking EC and HC from a medical provider.[22] Patients may be compelled to visit a pharmacy, rather than a medical provider, especially those who feel more comfortable seeking care from their local pharmacist, live in rural areas, lack insurance, or run out of refills. It is voluntary whether pharmacists choose to prescribe and although there are countless benefits, barriers also exist. Reported hurdles include the need for additional training, time and resource constraints associated with pharmacy workflow, safety concerns and increased liability, shortage of space to provide private counseling and screening, lack of corporate support, and absence of reimbursement for clinical services.[23,24] Pharmacist certification addresses the need for additional training, however, overcoming other hurdles will likely depend on corporate support and a reconceptualized community pharmacy framework. Pharmacists who chose to expand their roles must be aware of the barriers while advocating for safe and conducive environments to prescribe *and* dispense medications to patients.

General requirements for pharmacists prescribed HC and EC:

- Rule of 3: 3 screening documents must be filed and kept for 3 years
  - HC patient screening document
  - HC treatment algorithm
  - HC MEC for contraception
  - EC patient screening document
  - EC treatment algorithm
  - EC MEC, classifications for EC
- Blood pressure reading and medical history are required
- **No prescription if patient deviates from the questionnaires**
- HC prescription not to exceed 12 months
- HC dosage forms: oral, patch, intravaginal
- EC prescription is a one time fill
- EC options: OTC LNG or prescription UPA
- Pharmacist communication with primary care and/or OBGYN

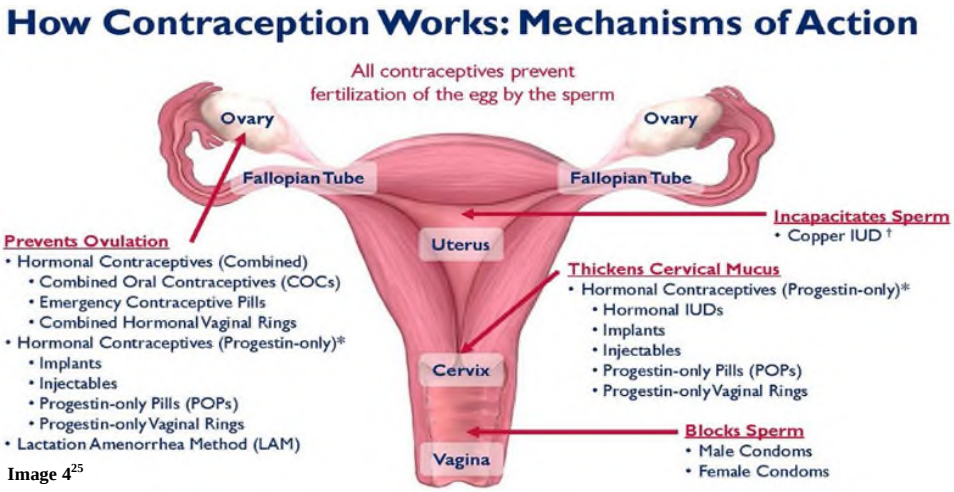


Image 4[25]

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December 2023
Published Quarterly by Kepro
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