NEWS FROM THE FDA/CDC

FDA approves first over-the-counter birth control pill

Damian McNamara, MA

The Food and Drug Administration's approval today of the first birth control pill for women to be available without a prescription is being hailed by many as a long-needed development, but there remain questions to be resolved, including how much the drug will cost and how it will be used.

The drug, Opill, is expected to be available early next year, and its maker has yet to reveal a retail price. It is the same birth control pill that has been available by prescription for 50 years. But for the first time, women will be able to buy the contraception at a local pharmacy, other retail locations, or online without having to see a doctor first.

Likely to drive debate

Contraception in the United States is not without controversy. The FDA's approval spurred reactions both for and against making hormonal birth control for women available without a prescription.

"It's an exciting time, especially right now when reproductive rights are being curtailed in a lot of states. Giving people an additional option for contraception will change people's lives," said Beverly Gray, MD, division director of Women's Community and Population Health at Duke University Medical Center in Durham, N.C.

https://www.mdedge.com/obgyn/news-fda/cdc

FEATURE

U.S. mammogram update sparks concern, reignites debates

Kerry Dooley Young

A recent update to the U.S. recommendations for breast cancer screening is raising concerns about the costs associated with potential follow-up tests, while also renewing debates about the timing of these tests and the screening approaches used.

The U.S. Preventive Services Task Force is currently finalizing an update to its recommendations on breast cancer screening. In May, the task force released a proposed update that dropped the initial age for routine mammogram screening from 50 to 40.

The task force intends to give a "B" rating to this recommendation, which covers screening every other year up to age 74 for women deemed average risk for breast cancer.

The task force's rating carries clout, A. Mark Fendrick, MD, director of the Value-Based Insurance Design at the University of Michigan, Ann Arbor, said in an interview.

For one, the Affordable Care Act requires that private insurers cover services that get top A or B marks from USPSTF without charging copays.

However, Dr. Fendrick noted, such coverage does not necessarily apply to follow-up testing when a routine mammogram comes back with a positive finding. The expense of follow-up testing may deter some women from seeking follow-up diagnostic imaging or biopsies after an abnormal result on a screening mammogram.

A recent analysis in JAMA Network Open found that women facing higher anticipated out-of-pocket costs for breast cancer diagnostic tests, based on their health insurance plan, were less likely to get that follow-up screening. For instance, the use of breast MRI decreased by nearly 24% between patients undergoing subsequent diagnostic testing in plans with the lowest out-of-pocket costs vs. those with the highest.

https://www.mdedge.com/obgyn/article/264198/breast-cancer/us-mammogram-update-sparks-concern-reignites-debates

GENDER-AFFIRMING GYNECOLOGY

Updates on pregnancy outcomes in transgender men

K. Ashley Brandt, DO

Despite increased societal gains, transgender individuals are still a medically and socially underserved group. The historic rise of antitransgender legislation and the overturning of *Roe v. Wade*, further compound existing health care disparities, particularly in the realm of contraception and pregnancy. Obstetrician-gynecologists and midwives are typically first-line providers when discussing family planning and fertility options for all patients assigned female at birth. Unfortunately, compared with the surgical, hormonal, and mental health aspects of gender-affirming care, fertility and pregnancy in transgender men is still a relatively

new and under-researched topic.

Only individuals who are assigned female at birth and have a uterus are capable of pregnancy. This can include both cisgender women and nonbinary/transgender men. However, societal and medical institutions are struggling with this shift in perspective from a traditionally gendered role to a more inclusive one. Obstetrician-gynecologists and midwives can serve to bridge this gap between these patients and societal misconceptions surrounding transgender men who desire and experience pregnancy.

Providers need to remember that many transmasculine individuals will still retain their uterus and are therefore capable of getting pregnant. While testosterone causes amenorrhea, if patients are engaging in penile-vaginal intercourse, conception is still possible. If a patient does not desire pregnancy, all contraceptive options available for cisgender women, which also include combined oral contraceptives, should be offered.

https://www.mdedge.com/obgyn/gender-affirming-gynecology

REPRODUCTIVE ROUNDS

Affordable IVF—Are we there yet?

Kevin Doody, MD; Mark Trolice, MD, MBA

The price for an in vitro fertilization (IVF) cycle continues to increase annually by many clinics, particularly because of "add-ons" of dubious value.

The initial application of IVF was for tubal factor infertility. Over the decades since 1981, the year of the first successful live birth in the United States, indications for IVF have dramatically expanded—ovulation dysfunction, unexplained infertility, male factor, advanced stage endometriosis, unexplained infertility, embryo testing to avoid an inherited genetic disease from the intended parents carrying the same mutation, and family balancing for gender, along with fertility preservation, including before potentially gonadotoxic treatment and "elective" planned oocyte cryopreservation·

The cost of IVF remains a significant, and possibly leading, stumbling block for women, couples, and men who lack insurance coverage. From RESOLVE.org, the National Infertility Association: "As of June 2022, 20 states have passed fertility insurance coverage laws, 14 of those laws include IVF coverage, and 12 states have fertility preservation laws for iatrogenic (medically induced) infertility." Consequently, "affordable IVF" is paramount to providing equal access for patients.

https://www.mdedge.com/obgyn/reproductive-rounds

CONFERENCE COVERAGE

'Artificial pancreas' for all type 1 diabetes pregnancies?

Marlene Busko

In the largest randomized controlled trial of an automated insulin delivery (AID) system (hybrid closed-loop) versus standard insulin delivery in pregnant women with type 1 diabetes, the automated CamAPS FX system prevailed.

The percentage of time spent in the pregnancy-specific target blood glucose range of 63-140 mg/dL (3.5-7.8 mmol/L) from 16 weeks' gestation to delivery was significantly higher in women in the AID group.

Helen R. Murphy, MD, presented these topline findings from the Automated Insulin Delivery Amongst Pregnant Women With Type 1 Diabetes (AiDAPT) trial during an e-poster session at the annual scientific sessions of the American Diabetes Association.

The "hybrid closed-loop significantly improved maternal glucose and should be offered to all pregnant women with type 1 diabetes," concluded Dr. Murphy, professor of medicine at the University of East Anglia and a clinician at Norfolk and Norwich University Hospital in the United Kingdom.

CamAPS FX is the only AID system approved in Europe and the United Kingdom for type 1 diabetes from age 1 and during pregnancy. The hybrid closed-loop system is not available in the United States but other systems are available and sometimes used off label in pregnancy. Such systems are sometimes known colloquially as an "artificial pancreas."

The researchers said their findings provide evidence for the UK National Institute of Clinical Excellence (NICE) to recommend that all pregnant women with type 1 diabetes should be offered the CamAPS FX system.

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