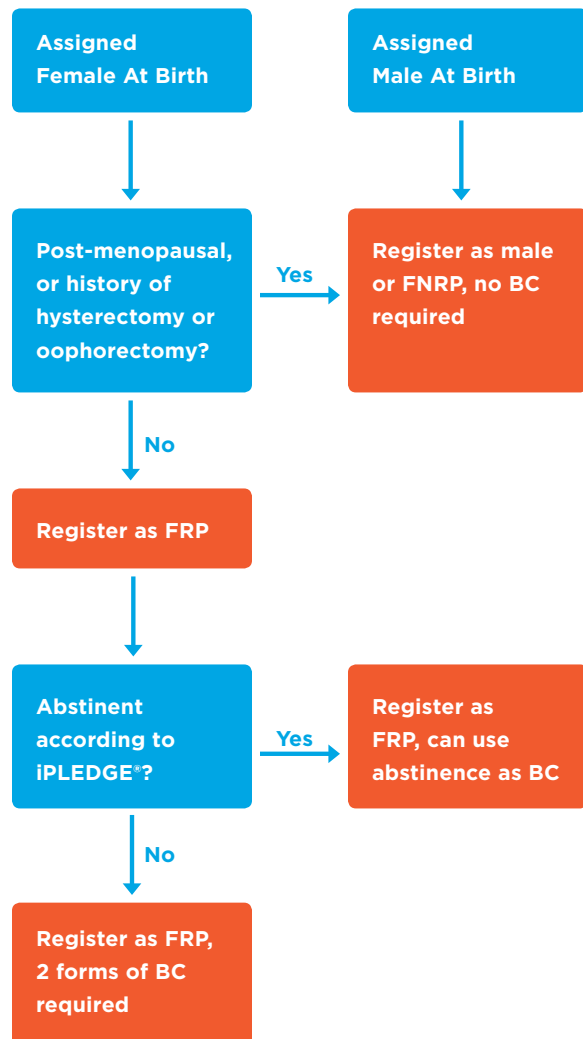


The following flowchart will help you determine whether or not you must register as FRP with iPLEDGE® and which birth control (BC) methods to use if you do:



Take-home Points

- Regardless of gender identity, iPLEDGE® requires anyone to register as a female of reproductive potential (FRP) if they were assigned female at birth and have the potential for pregnancy
- Two forms of birth control are required if you are registered as an FRP and are sexually active in a way that exposes you to sperm
- Anyone registered as a FRP will need a monthly pregnancy test
- You may register as a female of non-reproductive potential (FNRP) or as male if:
 - ✦ You were assigned male at birth OR
 - ✦ You have had hysterectomy, an oophorectomy, or are post-menopausal
- If you are enrolled as FNRP or male, you are not required to take birth control
- Testosterone therapy is not an effective means of birth control.

Resources

Visit fenwayhealth.org/transhealth and ipledgeprogram.com for more information.

Have More Questions?

If you are a patient at Fenway Health, contact your care team with any questions. Everyone else should contact transhealth@fenwayhealth.org.



A Guide to iPLEDGE®

For Trans and Gender Diverse Patients on Isotretinoin



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MG-123

DISCLAIMER: In this brochure, we use medical terminology to discuss genitals and reproductive potential. We understand that individuals may have other language they use to discuss these topics. Feel free to use any terms that best fit you when talking with providers about your body and healthcare needs.



Isotretinoin and Pregnancy

Isotretinoin (Accutane, Claravis, Absorbica, Amnesteem, Myorisan) is a drug used to treat acne that can lead to birth defects when taken during pregnancy. Anyone who is capable of becoming pregnant must take serious precautions while taking isotretinoin.

Many people who are started on isotretinoin therapy have the capacity for pregnancy, including those who are transgender, genderqueer, and non-binary. iPLEDGE® is a Risk Evaluation and Mitigation Strategy (REMS) program that the U.S. Food and Drug Administration (FDA) requires for certain medications. Unfortunately, iPLEDGE® does not recognize the diversity of gender identities and labels anyone with this reproductive potential as female. While it is contrary to what we know about gender diversity, anyone with the capacity to become pregnant must register through iPLEDGE® as a “female of reproductive potential” (FRP) to start isotretinoin therapy.

Registering in iPLEDGE®

If you were assigned male at birth, you can either register as a female of non-reproductive potential (FNRP) or as male, and you do not need birth control.

If you were assigned female at birth, you will need to register as a female of reproductive potential (FRP) unless one or more of the following applies:

- You have had a hysterectomy
- You have had a bilateral oophorectomy
- You are post-menopausal¹

If any of the above apply, you can register as a female of non-reproductive potential (FNRP) or male, and do not require birth control.

The following conditions DO NOT qualify for registering as a FNRP:

- Tubal Sterilization
- Abstinence
- Patient has not started menstruation

Those registered as a FRP need a monthly negative pregnancy test in order to get their medication from the pharmacy.

Testosterone Therapy and iPLEDGE®

Testosterone therapy is not an effective means of birth control and is not accepted by iPLEDGE® as a form of contraception.

Even with consistent use of testosterone therapy and cessation of menses, it is still possible for anyone with a uterus and ovaries to become pregnant.

Birth Control and iPLEDGE®

Anyone registered as a FRP on iPLEDGE® is required to be on birth control OR be abstinent while on isotretinoin. iPLEDGE® requires TWO forms of birth control, one primary birth control and another which can be either primary or secondary.

Primary Forms:

- Tubal sterilization (tying your tubes)
- Partner’s vasectomy
- Intrauterine device (IUD)
- Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)

Secondary Forms:

- Diaphragm with spermicide
- Cervical cap with spermicide
- Male latex condom
- Vaginal sponge

For transmasculine and non-binary individuals on testosterone, common forms of primary birth control may include an IUD, Depo-Provera shots, or Nexplanon implants. These are less likely to interfere with the masculinizing effects of testosterone.

Abstinence:

Abstinence is another option for patients who register as FRP in iPLEDGE®. iPLEDGE® defines abstinence as having “no sex or sexual contact with any male 24 hours a day, 7 days a week.”

You may be able to use abstinence if you:

- Are not sexually active
- Only have sexual contact with individuals who were assigned female at birth

¹ If you are not sure if this applies to you, speak with your medical provider about whether you qualify as a FNRP through this criterion.